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ABSTRACT

Otitis media with effusion and its related hearing loss have been associated with delayed language development, particularly if the disease is recurrent or of long duration, although available data are insufficient to establish a causal linkage. This guide presents recommendations based on extensive reviews of the relevant medical and health-related literature and on expert opinion and consensus of the interdisciplinary panel convened to develop the guide. Because the prevalence, incidence, and management of otitis media with effusion vary with the age of the patient, the guide focuses on the age group at high risk of long-term effects, ages 1 through 3. Recommendations are given for diagnosis and hearing evaluation; control of environmental factors; and sequencing of management interventions, including observation, use of antibiotics or other medications, and the appropriateness and time of surgery. Included are companion quick reference guides: "Managing Otitis Media with Effusion in Young Children" for clinicians; and "Middle Ear Fluid in Young Children" for parents. Contains a glossary and 158 references. (HTH)

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ED 382 306

Clinical Practice Guideline

Number 12

Otitis Media with Effusion in Young Children

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Clinical Practice Guideline
Otitis Media with Effusion
PS 022906

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Clinical Practice Guideline
Number 12

Otitis Media with Effusion in Young Children

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AHCPR Publication No. 94–0622
July 1994

Guideline Development and Use

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions. This guideline was written by an independent multidisciplinary panel of private-sector clinicians and other experts convened by the Agency for Health Care Policy and Research (AHCPR). The panel employed explicit, science-based methods and expert clinical judgment to develop specific statements on patient assessment and management for the clinical condition selected.

Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and field review were undertaken to evaluate the validity, reliability, and utility of the guideline in clinical practice. The panel's recommendations are primarily based on the published scientific literature. When the scientific literature was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants.

The guideline reflects the state of knowledge, current at the time of publication, on effective and appropriate care. Given the inevitable changes in the state of scientific information and technology, periodic review, updating, and revision will be done.

We believe that the AHCPR-assisted clinical guidelines will make positive contributions to the quality of care in the United States. We encourage practitioners and patients to use the information provided in this *Clinical Practice Guideline*. The recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients.

Linda K. Demlo, PhD
Acting Administrator
Agency for Health Care Policy and Research

Publication of this guideline does not necessarily represent endorsement by the U.S. Department of Health and Human Services.

Foreword

The past 15 years have shown a notable increase in the number of children identified as having otitis media (inflammation of the middle ear). According to the National Center for Health Statistics, otitis media is the most common diagnosis for physician office visits by children under age 15. Office visits for otitis media increased by 150 percent between 1975 and 1990, to 24.5 million, with children under age 15 accounting for 81 percent of the visits. Children under age 2 had the highest rate of visits to physician offices for otitis media, and they also had the greatest increase in visits between 1975 and 1990: 224 percent.

Otitis media is a general term for several conditions that can affect the middle ear, ranging from acute to chronic and with or without symptoms. To follow methods for practice guideline development recommended by the Agency for Health Care Policy and Research, the topic of this *Guideline* was narrowed to the management of otitis media with effusion in an otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits. This definition permitted examination of important medical and surgical interventions and their effects on long-term outcomes. In addition, 1 through 3 years is the critical age for development of speech and language, which may be affected by otitis media with effusion. The *Guideline* does not apply to children younger than age 12 months or, unless specifically noted, to children age 4 and above.

Otitis media with effusion is characterized by the presence of fluid in the middle ear without signs or symptoms of infection. Otitis media with effusion has also been referred to as noninfected middle ear effusion, secretory otitis media, and serous otitis media, among other terms. Although data on prevalence of otitis media with effusion as a separate condition were not available, the Panel estimated the prevalence of this condition as 25 to 35 percent of otitis media cases.

The medical interventions considered in the *Guideline* for management of otitis media with effusion in young children include antibiotic therapy, steroid therapy, and antihistamine/decongestant therapy; the surgical interventions studied include myringotomy with insertion of tympanostomy tubes, adenoidectomy, and tonsillectomy. Short-term outcomes addressed were resolution of effusion and restoration of hearing; the long-term outcomes studied were the effects of otitis media with effusion on hearing and hearing-related development of speech, language, and cognition. Because the prevalence of otitis media with effusion and the impact of associated hearing loss are greater among children with craniofacial or neurologic abnormalities, sensory deficits, or other medical illness, these children are excluded from *Guideline* recommendations.

A 1991 cost analysis of private health insurance claims, performed under contract for this *Guideline*, estimated direct and indirect medical

management costs (physician office visits, prescription medications, parents' time lost from work) at $406 per patient episode and direct and indirect surgical treatment costs (physician office visits, parents' time lost from work, and charges for myringotomy with insertion of tympanostomy tubes) at $2,174 per patient episode.

Although otitis media with effusion is exceedingly common, and thousands of research studies have been conducted, uncertainties persist regarding its etiology and management. Most cases of otitis media with effusion resolve spontaneously, but the length of time to resolution is variable. The long-term effects of the disease are not well understood. A mild to moderate conductive hearing loss can accompany otitis media with effusion. Hearing loss associated with frequent or prolonged episodes of otitis media with effusion might affect speech and language development, behavior, cognition, and academic achievement. Other ear problems, such as tympanic membrane perforation, might also occur with prolonged or frequent episodes of otitis media with effusion.

Uncertainties about the causes, diagnosis, and appropriate treatment of otitis media with effusion are reflected in variations in clinician practice patterns. The *Clinical Practice Guideline on Otitis Media with Effusion in Young Children* was written in response to these and other uncertainties, outlining an approach to the management of care for young children with this condition.

This *Guideline* was developed by the American Academy of Pediatrics, under contract with the Agency for Health Care Policy and Research (AHCPR) and in consortium with the American Academy of Family Physicians and the American Academy of Otolaryngology–Head and Neck Surgery (the "Consortium"). To develop the *Guideline*, the Consortium, with AHCPR approval, convened an interdisciplinary panel of pediatricians, family physicians, otolaryngologists, an infectious disease specialist, nurses, audiologists, speech/language pathologists, psychologists, a health policy analyst, and a consumer representative. The Panel defined and structured the problem and identified the important interventions and health outcomes. A critical review of the literature was conducted. Before the literature review was completed, an Open Meeting was held to obtain additional information on managing otitis media with effusion. After a careful analysis of the data, the Panel developed draft guidelines and conducted peer and pilot reviews. Comments from these reviews were assessed and used in the development of the final *Guideline*.

This is the first edition of the *Clinical Practice Guideline on Otitis Media with Effusion in Young Children*. The Consortium recognizes that issues surrounding the management of otitis media with effusion are complex and controversial. A revised *Guideline* will be produced when warranted by further research.

Otitis Media Guideline Panel

Abstract

Otitis media with effusion is one of the most common problems of infancy and early childhood and is responsible for substantial morbidity and expense. Most children will have one or more episodes during early childhood, and a significant number will have repeated episodes. Conductive hearing loss is frequent with this condition but is usually transient. Otitis media with effusion and its related hearing loss have been associated with delayed language development, particularly if the disease is recurrent or of long duration, although available data are insufficient to establish a causal linkage. Because the prevalence, incidence, and management of otitis media with effusion vary with the age of the patient, the Panel focused on the age group at high risk of these long-term effects of otitis media with effusion: children age 1 through 3 years. To promote appropriate management of otitis media with effusion in young children, the *Guideline* presents recommendations based on extensive reviews of the relevant medical and health-related literature and on expert opinion and Panel consensus. Recommendations are given for diagnosis and hearing evaluation; control of environmental factors; and sequencing of management interventions, including observation, use of antibiotics or other medications, and the appropriateness and timing of surgery.

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The Panel and Consortium acknowledge with special gratitude the contribution of William A. Gold, MD, MPH, of Lewin-VHI, Inc., who served the Panel faithfully as health policy analyst for the Guideline cost report until his death in October 1993.

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Executive Summary

This *Guideline* was developed by the American Academy of Pediatrics, under contract with the Agency for Health Care Policy and Research (AHCPR) and in consortium with the American Academy of Family Physicians and the American Academy of Otolaryngology–Head and Neck Surgery (the "Consortium"). To develop the *Guideline*, the Consortium, with AHCPR approval, convened an interdisciplinary non-Federal panel comprising health care professionals and a consumer representative.

The Agency for Health Care Policy and Research identified otitis media in children as a topic for clinical practice guideline development for several reasons. Otitis media has high prevalence and incidence among children in the United States. Widespread variations in practice patterns exist among generalists and specialists, and there are questions about the appropriateness and timing of treatment. Finally, the direct and indirect costs of diagnosing and managing otitis media are enormous: otitis media was the principal diagnosis for ambulatory care visits by young children, at an estimated cost of over $1 billion, in 1990-91.

The Otitis Media Guideline Panel viewed otitis media as a spectrum of diseases, ranging from acute to chronic and with or without symptoms. Otitis media can resolve spontaneously or respond to treatment. To examine issues of disease prevalence, management, and variations in treatment patterns for otitis media within the contract time frame, the Panel narrowed the scope of this *Guideline* to the management of otitis media with effusion in an otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits. This choice of condition allowed the Panel to examine a spectrum of management issues, including surgery. The age range for *Guideline* recommendations reflects the Panel's decision to examine treatment effects on the outcome of most widespread concern: alterations in hearing and associated development of speech, language, and cognition. The ages for *Guideline* recommendations were expanded when the data permitted, and in many instances the recommendations may be extrapolated to older children.

This *Guideline* is based on the relevant scientific literature and on the Panel's expert clinical opinion to support recommendations. The Consortium applied the Agency for Health Care Policy and Research's recommended methods to develop the *Guideline*. Using these methods, the Panel defined the problem and identified the alternatives for its management, the target population, the clinical settings in which the *Guideline* is to be applied, the important health outcomes, and the relationship of the outcomes to the alternatives for management. The definition of the problem guided the literature review. A systematic computerized search of the literature on otitis media with effusion was conducted. The Panel reviewed the data, synthesized the findings, and developed *Guideline* recommendations. Other sources of input into the

Guideline included the Panel's own expertise, information from Open Meeting presentations, peer and pilot reviewer comments, and Panel subcommittee analysis of the literature.

The Guideline addresses the following subjects:

- Natural history of otitis media with effusion.
- Functional impairments that may result from otitis media with effusion, and the difficulty of measuring the effects of medical and surgical interventions on long-term outcomes.
- Diagnosis and hearing evaluation for otitis media with effusion.
- Control of environmental risk factors that may contribute to the occurrence of the disease.
- Medical and surgical interventions for otitis media with effusion in the otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits. Interventions considered include observation, antibiotic therapy, steroid therapy, antihistamine/decongestant therapy, myringotomy with insertion of tympanostomy tubes, adenoidectomy, tonsillectomy, and allergy management.

Based on empirical evidence and their clinical experience and judgment, the Panel makes the following recommendations for the provision of care to a target group of patients with otitis media with effusion. The Panel recognizes the clinical circumstances of individual patients can require additional judgment of health care providers and parents regarding therapy.

- Initial management for effusion includes observation **OR** antibiotic therapy, and control of environmental risk factors.
- Management when effusion has persisted for a total of 3 months includes hearing evaluation. If hearing is in the normal range (better than 20 decibels hearing threshold level in the better-hearing ear), management includes observation **OR** antibiotic therapy and control of environmental risk factors. If a bilateral hearing deficit is present (20 decibels hearing threshold level or worse in the better-hearing ear), management includes antibiotic therapy **OR** bilateral myringotomy with insertion of tympanostomy tubes, and control of environmental risk factors.
- Management when effusion has persisted for 4 to 6 months with a bilateral hearing loss includes bilateral myringotomy with insertion of tympanostomy tubes and control of environmental risk factors.

1 Overview

The term otitis media refers to a broad range of clinical conditions, from acute to chronic, both asymptomatic and symptomatic. Otitis media occurs in all age groups and has many different causes. The Panel followed methods recommended by the Agency for Health Care Policy and Research to focus the *Otitis Media Clinical Practice Guideline* on a specific clinical problem. In narrowing the scope of the guideline project, the Panel sought to identify a specific condition that is prevalent, has been the subject of variation or controversy in management, and can have long-term effects on function. Otitis media with effusion in young children met these criteria: it is prevalent, its management is highly controversial, and it is thought by some experts to be associated with later language, learning, and behavioral problems.

Purpose and Scope of the *Guideline*

The purpose of the *Clinical Practice Guideline on Otitis Media with Effusion in Young Children* is to assist those who provide health care to young children in identifying and managing otitis media with effusion.

To meet constraints for *Guideline* development, the Panel focused the *Guideline* narrowly on management of otitis media with effusion in a "target child" age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits, otherwise healthy except for otitis media with effusion. In most cases, the Panel's findings regarding the effects of bilateral otitis media with effusion on hearing-related development and the timing of diagnostic tests/hearing evaluation and interventions to manage otitis media with effusion are described for this "target child." When possible, *Guideline* recommendations are broadened to include older children. The Panel also considered costs and availability of health care resources to manage otitis media with effusion in young children.

Organization of the *Guideline*

This first chapter of the *Guideline* provides background on otitis media with effusion, including prevalence of otitis media, and discusses the "target" patient for whom *Guideline* recommendations were formulated. Chapter 2 outlines the results of the Panel's evaluation of the literature on otitis media with effusion. The results are presented in the form of statements of options or recommendations and an algorithm for diagnosis, evaluation, and management. Chapter 3 presents the short-term and long-term outcomes of otitis media with effusion. Diagnostic issues regarding otitis media with effusion in children are addressed in Chapter 4.

Chapter 5 discusses control of environmental risk factors for otitis media with effusion. Chapter 6 reviews pharmaceutical interventions, and Chapter 7 reviews the Panel's findings regarding surgical interventions. Chapter 8 discusses results of the Panel's study of the association of allergy with otitis media with effusion, and Chapter 9 reviews findings regarding other treatments for this condition. Cost impacts of otitis media with effusion in children are presented in Chapter 10. In Chapter 11, research issues identified by the Panel are listed.

Target Population, Settings, and Providers of Care

Following methods recommended by the Agency for Health Care Policy and Research for guideline development, the Otitis Media Guideline Panel defined a "target patient" to narrow the scope of the literature review. The Panel also identified practice settings and providers of care to the target patient.

The target patient is a child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits, otherwise healthy except for otitis media with effusion.

The Panel developed the *Guideline* for use in any setting in which children at risk of otitis media with effusion would be identified or treated, including physician offices, outpatient clinics, hospital emergency departments or urgent care centers, and schools or child-care facilities.

The *Guideline* is intended for use by providers of health care to young children, including primary care and specialist physicians, professional nurses and nurse practitioners, physician assistants, audiologists, speech and language pathologists, child development specialists, and consumers.

Definition and Prevalence of Otitis Media with Effusion

The term otitis media (inflammation of the middle ear) encompasses a number of clinical conditions, each called by a variety of names. Statistics compiled by the National Center for Health Statistics (Schappert, 1992) and the results of longitudinal studies provide information about the incidence of and risk factors for otitis media.

Otitis media is the diagnosis made most frequently at visits by children younger than age 15 years to office-based physicians in the United States. Furthermore, the estimated 24.5 million visits for otitis media made in 1990 represented an increase of nearly 150 percent over the number of such visits made in 1975 (Schappert, 1992). In a large pediatric office practice in Boston, approximately one visit in three made for illness of any kind resulted in the diagnosis of middle ear disease; three-quarters of all followup visits for illness were made for disease of the middle ear (Teele, Klein, Rosner, et al., 1983).

A type of otitis media called otitis media with effusion is characterized by fluid in the middle ear without evidence of ear infection. Other terms used for otitis media with effusion in the literature include:

serous otitis media	mucoid otitis media	tympanic hydrops
secretory otitis media	secondary otitis media	glue ear
allergic otitis media	hydrotubotympanum	fluid ear
catarrhal otitis media	exudative catarrh	middle ear effusion
nonsuppurative otitis media	tubotympanitis	tubotympanic catarrh

The major symptoms associated with otitis media with effusion include discomfort and behavior changes.

The Panel did not find scientific evidence regarding the frequency with which the specific diagnosis of otitis media with effusion is made for children visiting ambulatory health care facilities in the United States. For the purposes of guideline development, the Panel estimated that in 25 to 35 percent of cases cited in the National Center for Health Statistics report (Schappert, 1992), the diagnosis "otitis media" represented otitis media with effusion.

The prevalence and natural history of otitis media with effusion have been reported in several research studies. However, much of the data include children in group child-care settings, which are a very select population. Also, the data include different, overlapping age groups. A 2-year study of 103 children age 2 to 6 years in group child care in the United States showed that 53 percent had at least one episode of otitis media with effusion during the first year of the study and 61 percent in the second year; 30 percent of the children had recurrent bouts of otitis media with effusion (Casselbrant, Brostoff, Cantekin, et al., 1985). A study of school children 5 to 12 years old found the incidence of otitis media with effusion to be much lower in children 6 years and older than in younger children (Casselbrant, Brostoff, Cantekin, et al., 1986), in keeping with the decreasing prevalence with increase in age reported by the National Center for Health Statistics (Schappert, 1992).

Otitis media with effusion cleared within 2 months in 80 percent of 103 children age 2 to 6 years in group child care in the United States (Casselbrant, Brostoff, Cantekin, et al., 1985). In a cohort study of 1,439 Dutch children, approximately 60 percent had recovered from the episode of otitis media with effusion without intervention after 3 months (Zielhuis, Straatman, Rach, et al., 1990). The latter clearance rate is cited throughout the *Guideline* because of the study's large sample size.

Methods for *Guideline* Development

The Consortium (American Academy of Pediatrics, American Academy of Family Physicians, and American Academy of Otolaryngology –Head and Neck Surgery) received 37 names from 32 organizations and 2 individuals for nomination to the interim panel. After review of the

nominations, the Consortium recommended a 15-member interim panel to the Agency for Health Care Policy and Research based on nominees' expertise, geographic location, race, and gender. Subsequently, a notice was published in the December 2, 1991, *Federal Register* and sent to the 32 organizations already solicited and 8 other organizations. From the resulting 18 additional panel nominations, the Consortium recommended adding 4 additional members to the panel. With Agency for Health Care Policy and Research approval, the Consortium appointed an Otitis Media Guideline Panel consisting of 17 Panel members and 2 Panel co-chairs. The Panel held four 2-day meetings over a 14-month period.

The Panel based their approach to guideline development on Agency for Health Care Policy and Research recommendations and the principles of Eddy (1992). The Panel was introduced to Eddy's principles of evidence-based clinical policy development at its first two meetings. Using these methods, the Panel (1) specified clearly the clinical questions to be addressed by the *Guideline*, which was achieved by identifying the "target patient" and listing the interventions and outcomes to be explored; (2) developed literature search strategies; (3) examined the literature critically; and (4) developed evidence tables based on the data extracted from the literature review.

The Panel divided into subcommittees to examine the data on interventions for otitis media with effusion. Each subcommittee determined the type of data that would be acceptable for inclusion in the evidence regarding the intervention. The subcommittees examining pharmaceutical or surgical interventions accepted only randomized, blinded, controlled studies for inclusion in the evidence for these interventions. For diagnostic interventions, the subcommittee reviewed the diagnostic gold standard pursuant to deciding which studies to include in the evidence. For control of environmental risk factors, the subcommittee looked for high-quality epidemiologic studies. For speech, language, and developmental outcomes, controlled studies that documented accurate diagnosis of otitis media with effusion in the target population of children were accepted for inclusion in the evidence.

The Panel also appointed subcommittees as necessary to review controversial areas, such as speech and language development and antibiotic treatment of otitis media with effusion. The report of the Subcommittee for Scientific Assessment, which reviewed the data on antibiotic treatment, is included in the *Guideline Technical Report*. Furthermore, the Panel and contractors guided and assisted those subcontracted to conduct the literature review (Children's Hospital of Pittsburgh), to perform the cost analysis (Lewin-VHI, Inc.), and to provide technical writing services (Children's Hospital of Pittsburgh).

The literature search was conducted using the on-line bibliographic data base of the National Library of Medicine and 10 specialized bibliographic data bases. The data bases searched, the search strategies, and the results are detailed in the *Guideline Technical Report*. Initial

searches resulted in identification of 3,578 bibliographic citations, for which 1,362 abstracts were obtained and evaluated. Based on the initial review, 378 full-text articles were selected for data extraction using a nine-page form developed by the methodologist and Panel. More than 100 additional bibliographic citations were identified through review of literature reference lists, updated on-line searches, requests to professionals, and suggestions from experts. The interim panel chair also contacted numerous professional organizations to solicit unpublished data on this topic. The *Guideline* includes 158 references. In addition, the Panel sought information about otitis media with effusion by holding an Open Meeting that was announced in the *Federal Register*. Twelve oral testimonies were presented, eight of which were also written; additionally, twelve written testimonies were provided.

For each article considered for inclusion in the evidence, two different individuals extracted data, thus creating two records for each article in the data base. Because of the controversy regarding otitis media research at the University of Pittsburgh, all articles with a connection to the University of Pittsburgh were reviewed and data extracted by an independent professional. Literature review results were entered into a dBase (Ashton-Tate, Torrance, CA) data base with more than 720 fields. Entries in the data base were then corrected to eliminate any differences between extractions. The Panel reviewed the evidence in the data base and focused attention on randomized, blinded, controlled clinical studies wherever possible, although such evidence was not available in all areas of investigation. The Panel conducted an additional literature search and evaluation in the area of speech, language, and behavioral outcomes of otitis media with effusion. When possible, literature relevant to a given outcome was subjected to meta-analysis using FAST*PRO (Eddy and Hasselblad, 1992) to combine data by either Bayesian or hierarchical Bayesian techniques. To ensure against bias, meta-analysis of the data on antibiotic treatment of otitis media with effusion was reviewed by an independent expert.

During parts of each meeting, the Panel divided into subgroups to expedite the process of reviewing literature and making recommendations on diagnosis and the clinical interventions examined. Special subcommittees worked between Panel meetings to examine certain issues in greater depth, especially those of antibiotic treatment and of long-term outcomes. All deliberations of subgroups were brought back to the full Panel for discussion, revision, and approval. During Panel meetings, sessions were chaired by the co-chairs and the methodologist. The goal was to reach consensus on every decision. When consensus was not possible, votes were taken. If fewer than four Panel members disagreed with the decision, the decision was carried forward without comment. Many topics covered in the *Guideline* are controversial and remained so after review of the scientific evidence. Some Panel members strongly dissented from the majority opinion on individual recommendations and

have written minority comments, included in an appendix to the *Guideline Technical Report*.

The paragraph below presents the grading system the Panel developed and summarizes the outcome of their deliberations regarding diagnostic and treatment interventions for otitis media with effusion in the target child. Of note is that the final recommendations are at least partially subjective, notwithstanding the level of objective scientific evidence for or against the recommendation. First, judgments about the quality of the science could not be fully objective; members of the Panel differed significantly in their individual judgments on issues such as long-term outcomes and the use of steroid and antibiotic medications, for example, even though all were evaluating the same data base. Second, the Panel occasionally linked weaker scientific evidence with strong theoretical arguments to construct a strong recommendation. An example is the recommendation regarding obtaining a hearing test before myringotomy and insertion of tympanostomy tubes. Each recommendation in the *Guideline* includes a statement about the basis for the Panel's decision.

Panel Recommendations and Levels of Evidence

Although the Panel chose the target patient as a child age 1 through 3 years, the literature review showed that some of the recommendations could apply to older children. All the recommendations presented here are limited, however, to children with no craniofacial or neurologic abnormalities or sensory deficits (except as specifically noted in the recommendations) and who are healthy except for otitis media with effusion.

Individual recommendations were graded by the Panel as follows:

- **Recommendations** were made for interventions that the Panel took a stand for or against:

  Strong recommendations were based on high-quality scientific evidence or, in the absence of high-quality scientific evidence, on strong Panel consensus.

  Moderate recommendations were based on good-quality scientific evidence or, in the absence of good-quality scientific evidence, on expert opinion of the Panel.

  Recommendations not otherwise specified were based on limited scientific evidence or, in the absence of scientific evidence, on expert opinion of the Panel.

- **Clinical options** were identified as interventions that the Panel failed to find compelling evidence for or against. Clinical options are interventions that a reasonable health care provider might or might not wish to implement in his or her practice.

- **No recommendation** was made when scientific evidence was lacking and there was no compelling reason to make an expert judgment.

2 Guideline: Summary of Recommendations

The Panel developed clinical options and made recommendations for diagnosis, evaluation, and management of otitis media with effusion in otherwise healthy children ages 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits. The recommendations are based on the results of the literature review and the expert opinion of the Panel. They are summarized here, followed by a corresponding algorithm. Details and rationale for the recommendations are given in subsequent chapters.

Diagnosis of Otitis Media with Effusion and Evaluation of Hearing

- **Pneumatic Otoscopy—Recommendation:** The diagnostic evaluation of suspected otitis media with effusion should include pneumatic otoscopy. Otoscopy alone (without the use of the pneumatic otoscope to test tympanic membrane mobility) is not recommended. *[Strong recommendation based on limited scientific evidence and strong Panel consensus.]*
- **Tympanometry—Option:** Tympanometry may be used as a confirmatory test for otitis media with effusion. *[Option based on limited scientific evidence and expert opinion.]*
- **Acoustic Reflectometry—No Recommendation:** No recommendation is made regarding the use of acoustic reflectometry as a screening or diagnostic test for otitis media with effusion.
- **Tuning Fork Tests—No Recommendation:** No recommendation is made regarding the use of tuning fork tests in screening for or diagnosis of otitis media with effusion, except to note that they are inappropriate in the youngest children.
- **Hearing Evaluation—Option:** Hearing evaluation may be performed before otitis media with effusion has been present for a total of 3 months. *[Option based on insufficient evidence.]*
- **Hearing Evaluation—Recommendation:** Hearing evaluation is recommended for a child who has had bilateral otitis media with effusion for a total of 3 months. *[Recommendation based on limited scientific evidence and expert opinion.]*

Management

The Panel decided upon options and made recommendations for management of the otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits (except as noted in the recommendations) who enters the management algorithm with otitis media with effusion. Management is discussed for (1) initial presentation, (2) after a total of 3 months of otitis media with effusion, and (3) when otitis media with effusion has continued for a total of 4 to 6 months. These guidelines may be modified to fit the needs of the individual patient.

Visit Interval

The Panel found no evidence regarding optimal visit intervals. A visit interval of 6 weeks was assumed in preparing these recommendations.

Initial Management

- **Observation OR Antibiotic Therapy—Option:** Observation **OR** antibiotic therapy may be chosen for management of otitis media with effusion in an otherwise healthy child. *[Option based on limited scientific evidence and Panel consensus.]*
- **Environmental Risk Factor Control—Option:** Parents should be encouraged to control environmental risk factors. *[Option based on limited scientific evidence and strong Panel consensus.]*
- **Myringotomy—Recommendation:** Myringotomy with or without insertion of tympanostomy tubes should **NOT** be performed for initial management of otitis media with effusion in an otherwise healthy child. *[Strong recommendation based on evidence that otitis media with effusion resolves spontaneously in most cases and lack of conclusive evidence that a short period of otitis media with effusion has deleterious effects on otherwise healthy children.]*

After 3 Months

If the child has hearing in the normal range, as indicated by a hearing threshold level better than 20 decibels in the better-hearing ear, recommendations are as follows:

- **Observation OR Antibiotic Therapy—Option:** Observation **OR** antibiotic therapy may be chosen. *[Option based on limited scientific evidence and Panel consensus.]*
- **Environmental Risk Factor Control—Option:** Parents should be encouraged to control environmental risk factors. *[Option based on limited scientific evidence and strong Panel consensus.]*

If the child has bilateral hearing deficits of 20 decibels hearing threshold level or worse, recommendations are as follows:

- **Antibiotic Therapy OR Myringotomy with Tubes—Option:** Antibiotic therapy **OR** bilateral myringotomy with insertion of tympanostomy tubes may be chosen to manage bilateral otitis media with effusion that has lasted a total of 3 months in an otherwise healthy child age 1 through 3 years who has a bilateral hearing deficit (defined as 20 decibels hearing threshold level or worse in the better-hearing ear). *[Based on limited scientific evidence and Panel consensus.]*
- **Environmental Risk Factor Control—Option:** Parents should be encouraged to control environmental risk factors. *[Option based on limited scientific evidence and strong Panel consensus.]*

After 4 to 6 Months

- **Myringotomy with Tubes—Recommendation:** Bilateral myringotomy with insertion of tympanostomy tubes is recommended to manage bilateral otitis media with effusion that has lasted a total of 4 to 6 months in an otherwise healthy child age 1 through 3 years who has bilateral hearing deficit (defined as 20 decibels hearing threshold level or worse in the better-hearing ear). *[Moderate recommendation based on limited scientific evidence and strong Panel consensus.]*
- **Environmental Risk Factor Control—Option:** Parents should be encouraged to control environmental risk factors. *[Option based on limited scientific evidence and strong Panel consensus.]*

Not Recommended at Any Time

- **Steroid Therapy—Recommendation:** Steroid medications are not recommended for treatment of otitis media with effusion in a child of any age. *[Based on limited scientific evidence and Panel majority opinion.]* The Panel makes no statement regarding the use of steroid medications for conditions other than otitis media with effusion.
- **Antihistamine/Decongestant Therapy—Recommendation:** Antihistamine and/or decongestant agents are not recommended for treatment of otitis media with effusion. *[Strong recommendation based on evidence that can be generalized to a child of any age.]* The Panel makes no statement regarding the use of antihistamine and/or decongestant medications for conditions other than otitis media with effusion.
- **Adenoidectomy—Recommendation:** Adenoidectomy is not recommended for treatment of otitis media with effusion in a child age 1 through 3 years in the absence of specific adenoid pathology. *[Based on limited scientific evidence and Panel majority opinion.]*

- **Tonsillectomy—Recommendation:** Tonsillectomy should not be performed, either alone or with adenoidectomy, for the treatment of otitis media with effusion in a child of any age. *[Strong recommendation based on limited scientific evidence and strong Panel consensus.]*

No Recommendation

- **Allergy Management—No Recommendation:** No recommendation is made regarding allergy management as treatment for otitis media with effusion in the otherwise healthy child age 1 through 3 years. *[Based on insufficient evidence clarifying the relationship between allergy and otitis media with effusion.]*
- **Other Therapies—No Recommendation:** No recommendation is made regarding other therapies (chiropractic, holistic, naturopathic, traditional or indigenous, homeopathic) for the treatment of otitis media with effusion in the otherwise healthy child age 1 through 3 years. *[Based on lack of scientific evidence.]*

Algorithm

The notes below are an integral part of the algorithm that follows.

Notes to Algorithm

(A) Otitis media with effusion (OME) is defined as fluid in the middle ear without signs or symptoms of infection; OME is not to be confused with acute otitis media (inflammation of the middle ear with signs of infection). The Guideline and this algorithm apply **ONLY** to the child age 1 through 3 years with no craniofacial or neurologic abnormalities of sensory deficits who is otherwise healthy except for otitis media with effusion. For the purpose of this algorithm, the Panel assumed followup intervals of 6 weeks.

(B) The algorithm applies only to a child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits (except as noted) who is healthy except for otitis media with effusion. The Guideline recommendations and algorithm **DO NOT** apply if the child has any craniofacial or neurologic abnormality (for example, cleft palate or mental retardation) or sensory deficit (for example, decreased visual acuity or pre-existing hearing deficit).

(C) Pneumatic otoscopy is defined and described in Chapter 4, "Diagnosis and Hearing Evaluation" (page 29), and in the Glossary. The Panel found some evidence, reported in Chapter 4, that pneumatic otoscopy is more accurate than otoscopy performed without the pneumatic test of eardrum mobility.

(D) Tympanometry and hearing evaluation are discussed in Chapter 4 and defined in the Glossary. Tympanometry (page 32) may be used as confirmation of pneumatic otoscopy (page 30) in the diagnosis of otitis media with effusion (OME). Hearing evaluation (page 35) is recommended for the otherwise healthy child who has had bilateral OME for 3 months; before 3 months, hearing evaluation is a clinical option.

(E) In most cases, otitis media with effusion (OME) resolves spontaneously within 3 months (Zielhuis, Straatman, Rach, et al., 1990).

(F) The antibiotic drugs studied for treatment of otitis media with effusion (OME) were amoxicillin, amoxicillin-clavulanate potassium, cefaclor, erythromycin, erythromycin-sulfisoxazole, sulfisoxazole, and trimethoprim-sulfamethoxazole. The Panel's findings regarding antibiotic drugs for OME are given in Chapter 6, "Pharmaceutical Therapies" (page 41).

(G) Exposure to cigarette smoke (passive smoking) has been shown to increase the risk of otitis media with effusion (OME), as documented in Chapter 5, "Control of Environmental Risk Factors" (page 37). For bottle-feeding versus breast-feeding and for child-care facility placement, associations were found with OME, but evidence available to the Panel did not show decreased incidence of OME with breast-feeding or with removal from child-care facilities.

(H) The recommendation against tonsillectomy is based on the lack of added benefit from tonsillectomy when combined with adenoidectomy to treat otitis media with effusion in older children. Tonsillectomy and adenoidectomy may be appropriate for reasons other than otitis media with effusion. See Chapter 7, "Surgical Therapies" (page 55).

(I) The Panel found evidence that decongestants and antihistamines are ineffective treatments for otitis media with effusion, as documented in Chapter 6, "Pharmaceutical Therapies" (pages 53-54).

(J) Meta-analysis failed to show a significant benefit for steroid medications without antibiotic medications in treating otitis media with effusion in children, as reported in Chapter 6, "Pharmaceutical Therapies" (pages 50-53).

Figure 1. Algorithm for managing otitis media with effusion in an otherwise healthy child age 1 through 3 years

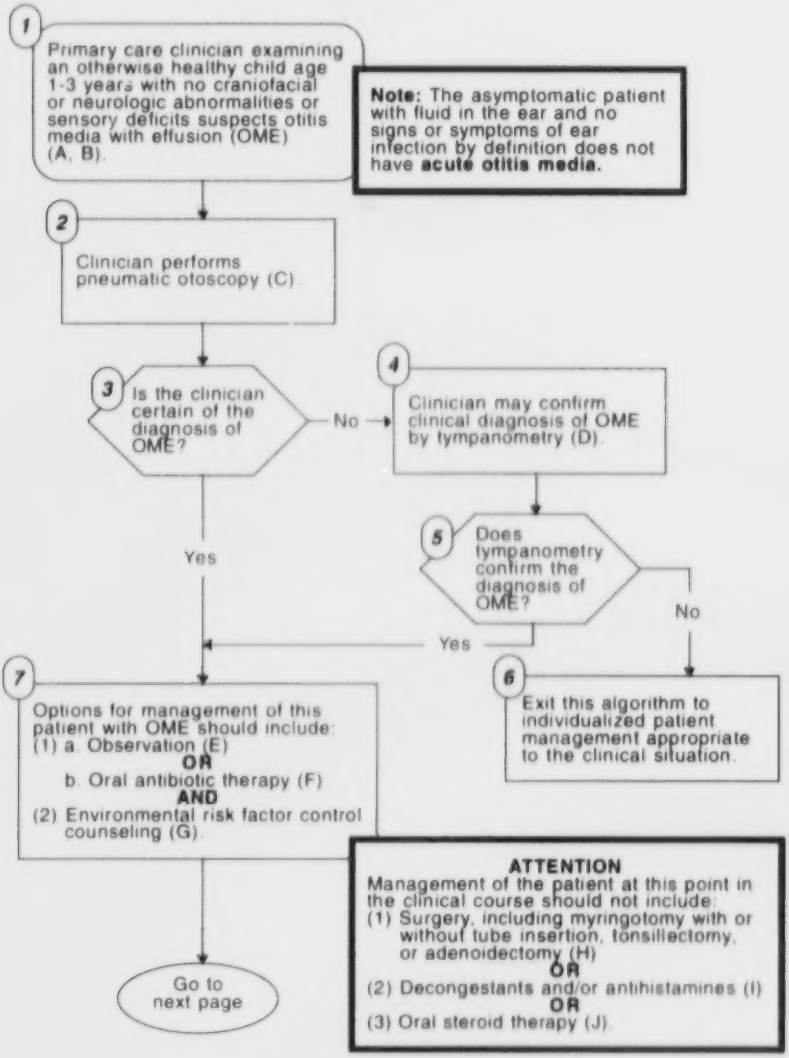

1
Primary care clinician examining an otherwise healthy child age 1-3 years with no craniofacial or neurologic abnormalities or sensory deficits suspects otitis media with effusion (OME) (A, B).
Note: The asymptomatic patient with fluid in the ear and no signs or symptoms of ear infection by definition does not have acute otitis media.
2
Clinician performs pneumatic otoscopy (C).
3
Is the clinician certain of the diagnosis of OME?
No
4
Clinician may confirm clinical diagnosis of OME by tympanometry (D).
Yes
5
Does tympanometry confirm the diagnosis of OME?
No
Yes
6
Exit this algorithm to individualized patient management appropriate to the clinical situation.
7
Options for management of this patient with OME should include:
(1) a. Observation (E)
OR
b. Oral antibiotic therapy (F)
AND
(2) Environmental risk factor control counseling (G).
ATTENTION
Management of the patient at this point in the clinical course should not include:
(1) Surgery, including myringotomy with or without tube insertion, tonsillectomy, or adenoidectomy (H)
OR
(2) Decongestants and/or antihistamines (I)
OR
(3) Oral steroid therapy (J).
Go to next page

Figure 1 (continued)

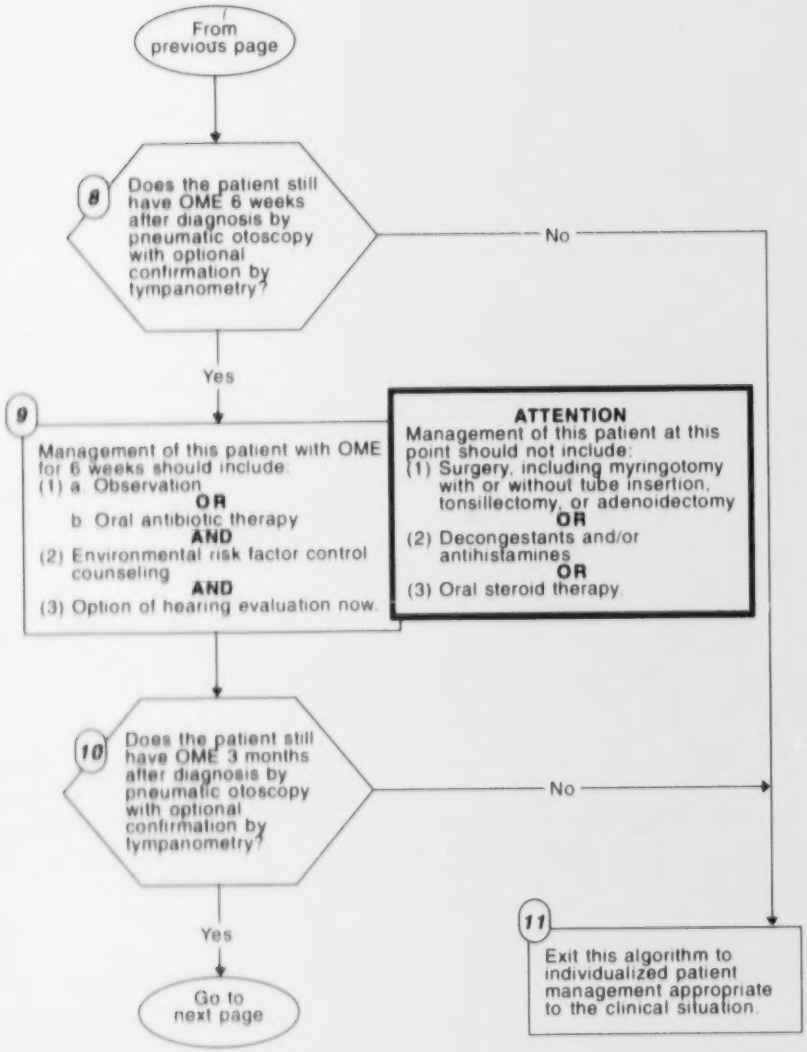
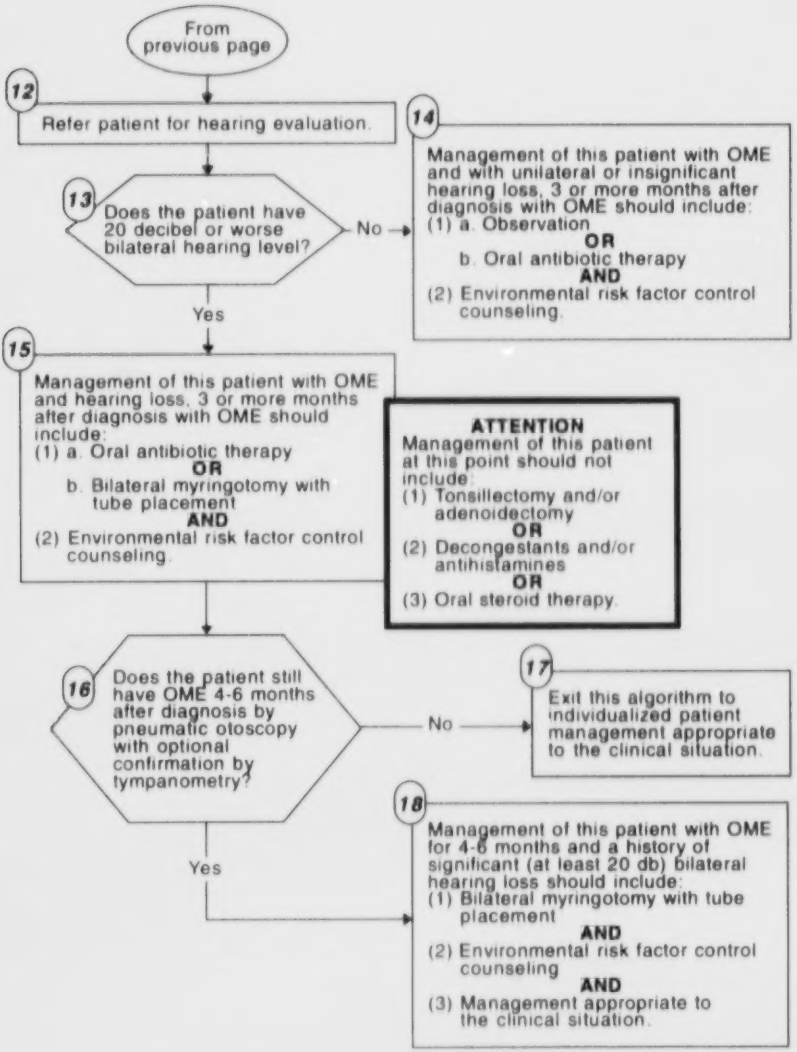

From previous page
8
Does the patient still have OME 6 weeks after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?
No
Yes
9
Management of this patient with OME for 6 weeks should include:
(1) a. Observation
OR
b. Oral antibiotic therapy
AND
(2) Environmental risk factor control counseling
AND
(3) Option of hearing evaluation now.
ATTENTION
Management of this patient at this point should not include:
(1) Surgery, including myringotomy with or without tube insertion, tonsillectomy, or adenoidectomy
OR
(2) Decongestants and/or antihistamines
OR
(3) Oral steroid therapy
10
Does the patient still have OME 3 months after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?
No
Yes
Go to next page
11
Exit this algorithm to individualized patient management appropriate to the clinical situation.

Figure 1 (continued)


From previous page
12
Refer patient for hearing evaluation.
13
Does the patient have 20 decibel or worse bilateral hearing level?
No
Yes
14
Management of this patient with OME and with unilateral or insignificant hearing loss, 3 or more months after diagnosis with OME should include:
(1) a. Observation
OR
b. Oral antibiotic therapy
AND
(2) Environmental risk factor control counseling.
15
Management of this patient with OME and hearing loss, 3 or more months after diagnosis with OME should include:
(1) a. Oral antibiotic therapy
OR
b. Bilateral myringotomy with tube placement
AND
(2) Environmental risk factor control counseling.
ATTENTION
Management of this patient at this point should not include:
(1) Tonsillectomy and/or adenoidectomy
OR
(2) Decongestants and/or antihistamines
OR
(3) Oral steroid therapy.
16
Does the patient still have OME 4-6 months after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?
No
17
Exit this algorithm to individualized patient management appropriate to the clinical situation.
Yes
18
Management of this patient with OME for 4-6 months and a history of significant (at least 20 db) bilateral hearing loss should include:
(1) Bilateral myringotomy with tube placement
AND
(2) Environmental risk factor control counseling
AND
(3) Management appropriate to the clinical situation.

3 Guideline: Clinical Outcomes Addressed

The development of recommendations for otitis media with effusion is complicated by a lack of sufficient data about the most important outcomes. Otitis media with effusion is very common in young children; however, most effusions (about 60 percent in one large study; Zielhuis, Straatman, Rach, et al., 1990) spontaneously resolve by 3 months. The major short-term outcomes (weeks to months) that have been identified include discomfort and behavior changes; the long-term outcomes (months to years) of concern are the impact of hearing loss on speech and language development, with possible deficits in language, speech, learning, and behavior. For children who undergo myringotomy with insertion of tympanostomy tubes, adverse long-term outcomes may include changes in the tympanic membrane, such as tympanosclerosis and persistent perforation. The Panel identified cholesteatoma, mastoiditis, and inner ear damage as other possible long-term effects of otitis media with effusion, but these problems apparently occur so rarely that they were not reported in the controlled studies evaluated by the Panel.

The Panel also found inadequate evidence in the literature regarding short- and long-term effects of treatment on speech, language, discomfort, and behavior to permit direct estimation of treatment effects on these outcomes. Instead, studies reported in the literature focused on an intermediate outcome of treatment, clearance of the middle ear effusion.

Short-Term Outcomes

Table 1 shows the relative benefits and harms of the treatment interventions the Panel examined for otitis media with effusion in a young child. The estimates of benefits and harms are shown as differences from the base case—a target patient (a child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits who is otherwise healthy except for otitis media with effusion) whose otitis media with effusion is managed by observation. These differences are shown rather than actual study results, because studies differed in the rate at which otitis media with effusion cleared in the control arms. Where high-quality evidence on the probability or magnitude of an effect was available, the results are shown as a median and 95 percent confidence interval of the distribution that resulted from meta-analysis. More information about the estimates is contained in the sections of the Guideline that deal with the specific intervention; greater detail is provided in the *Guideline Technical Report*.

Table 1. Outcomes of treating otitis media with effusion[1]

Intervention	Benefits[2]	Harms[2]
Observation	Base case.	Base case.
Antibiotics	Improved clearance of effusion at 1 month or less, 14.0% (95% CI [3.6%,24.2%]). Possible reduction in future infections.	Nausea, vomiting, diarrhea (2%-32% depending on dose and antibiotic). Cutaneous reactions (≤5%). Numerous rare organ system effects, including very rare fatalities. Cost. Possible development of resistant strains of bacteria.
Antibiotics plus steroids	Possible improved clearance at 1 month, 25.1% (95% CI [-1.3%,49.9%]).[3] Possible reduction in future infections.	See antibiotics and steroids separately.
Steroids alone	Possible improved clearance at 1 month, 4.5% (95% CI [-11.7%, 20.6%]).[3]	Possible exacerbation of varicella. Long-term complications not established for low doses. Cost.
Antihistamine/ decongestant	Same as base case.	Drowsiness and/or excitability.[4] Cost.
Myringotomy with tubes	Immediate clearance of effusion in all children. Improved hearing.	Invasive procedure. Anesthesia risk. Cost. Tympanosclerosis. Otorrhea. Possible restrictions on swimming.
Adenoidectomy	Benefits for young children have not been established.	Invasive procedure.[4] Anesthesia risk. Cost.
Tonsillectomy	Same as base case.	Invasive procedure.[4] Anesthesia risk. Cost.

[1] The target patient is an otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits.
[2] Outcomes are reported as differences from observation, which is treated as the base case. When possible, meta-analysis was performed to provide a mean and associated confidence interval (CI).
[3] Difference from base case not statistically significant.
[4] Risks were not examined in detail because no benefits were identified.

Long-Term Outcomes

Studies that link otitis media with effusion with hearing-related development did not use consistent measures of otitis media with effusion, hearing loss, and outcomes. However, the published data support the following trends: (1) a weak association between otitis media with effusion early in life and abnormal speech and language development of children younger than age 4 years; and (2) a weak association between early otitis media with effusion and delay in expressive language development and behavior (attention) in children over age 4 years. The effects of otitis media with effusion on other hearing-related domains are less clear.

The association between congenital or early-onset hearing impairment, particularly sensorineural hearing loss, and impaired speech and language development is well established (Ventry, 1980; Nober, 1967; Matkin, 1968): the earlier the onset and the more severe the hearing impairment, the greater the impairment in development of speech and language. Permanent sensorineural or conductive hearing loss leads to pronounced abnormalities in speech and language acquisition. In contrast, otitis media with effusion can produce mild to moderate conductive hearing impairment, which can fluctuate, remain stable, or alternate with periods of normal hearing. It is not known how many days of effusion and reduced hearing are required before development is adversely affected. Nevertheless, because permanent hearing loss can markedly affect communication, clinicians have hypothesized that the hearing impairment associated with persistent or recurrent episodes of otitis media with effusion at an early age may produce significant speech, language, cognitive, and educational delays and have advocated early, aggressive treatment of otitis media with effusion in young children. Thus, the Panel addressed this issue with particular interest, and rigorously reviewed and analyzed the available literature on hearing-related developmental outcomes of treated and untreated otitis media with effusion.

A search of the literature identified 101 published articles: 71 contained original data and 30 were review, anecdotal, or theoretical articles. None reported randomized, controlled clinical studies. The 71 articles with original data were examined in further detail: all but 35 were excluded from further consideration because: (1) they did not present sufficient developmental data; (2) otitis media with effusion was not documented before age 4; (3) researchers relied entirely on parental report for otitis media with effusion history; (4) they were retrospective studies that focused on children with speech disorders, language disorders, and/or learning disabilities; or (5) children had a biologic condition (such as cleft palate) that increased their risk of otitis media with effusion.

The 35 remaining studies were then classified with attention to the rigor of the experimental design, sample characteristics as they relate to the

target population of this Guideline, and statistical analysis. Fourteen of the studies were considered adequate, and 11 were characterized by some limitation in methods such as retrospective design, use of medical record review to document otitis media with effusion history, or inclusion of a population at high risk. The remaining 10 had significant flaws that could compromise the validity of the results and their interpretation. Taken as a group, the principal characteristic of the 21 "suboptimal" studies was the presence of inconclusive and often contradictory results. Meta-analysis of the 14 adequate studies was not possible because of the marked diversity of measurement tools used for outcome assessment, as well as a lack of uniformity in the ways in which the data were presented. The Panel used expert opinion to judge the evidence (summarized in Table 2) addressing the following four main issues.

Does Untreated Otitis Media with Effusion Affect Speech, Language, and Development?

Zielhuis, Straatman, Rach, et al. (1990) reported that approximately 60 percent of the cases of otitis media with effusion resolved spontaneously without intervention within 3 months of onset, and 85 percent within 6 months. It is not clear, however, whether children whose effusions resolved by 3 months were still free of effusion at 6 months. The major long-term outcomes used to justify early and aggressive treatment of otitis media with effusion are developmental delays or deficits that might result from the mild to moderate hearing losses that often accompany middle ear effusions. The literature on this subject, however, does not present a uniform picture: the findings of different studies are contradictory.

The Panel found several studies that reported lower scores for children with histories of early, recurrent otitis media with effusion versus children without such histories on tests of vocabulary (Teele, Klein, Rosner, et al., 1984), auditory comprehension (Rach, Zielhuis, van Baarle, et al., 1991; Gravel and Wallace, 1992; Lous, Fiellau-Nikolajsen, and Jeppesen, 1988), semantics and syntax (Rach, Zielhuis, and van den Broek, 1988), auditory figure-ground discrimination (Gravel and Wallace, 1992), narrative skill (Feagans, Sanyal, Henderson, et al., 1987), and other discrete receptive and expressive language skills (Friel-Patti, Finitzo-Hieber, Conti, et al., 1982; Friel-Patti and Finitzo, 1990; Teele, Klein, Rosner, et al., 1984). Specific articulation and phonological errors have been described as well (Roberts, Burchinal, Koch, et al., 1988).

Other studies, however, have failed to find significant differences in some of these measures, even when using the same test instruments (Roberts, Sanyal, Burchinal, et al., 1986; Roberts, Burchinal, Davis, et al., 1991; Wright, Sell, McConnell, et al., 1988; Lous, Fiellau-Nikolajsen, and Jeppesen, 1988).

typically produces a hearing loss most prominent for the low frequencies (below 1,000 Hz), auditory brainstem response recording has the potential to underestimate the degree of hearing loss from otitis media with effusion.

Although some reports specify details of hearing loss associated with otitis media with effusion, the available literature taken as a whole does not permit reliable estimates of the course of hearing loss during episodes of effusion. The literature also fails to provide information needed to estimate to what degree parameters of hearing loss (frequency, severity, and duration of loss; frequency and duration of periods of normal hearing; age of onset) influence speech, language, and other developmental outcomes. In general, hearing status appears to be a better predictor of developmental outcomes than does otitis media with effusion: that is, the literature points to a direct connection between hearing and language, and an indirect connection between otitis media with effusion and language, mediated by the relationship between otitis media with effusion and hearing (Friel-Patti and Finitzo, 1990). Empirical research to test this hypothesis is unlikely to be conducted, however, because of the difficulty of quantifying effects due to duration and severity of otitis media with effusion on the one hand and effects due to parameters of hearing loss on the other.

Many clinicians have tried to measure the effects on speech and language of hearing loss related to otitis media with effusion, but few agree as to which tests should be used to measure those functions: one review article identified 15 different language tests used in only 20 studies. Furthermore, the results varied among studies, even when the same test was used (Roberts, Burchinal, Davis, et al., 1991). For example, significant differences in performance on the Peabody Picture Vocabulary Test were found by some investigators (Holm and Kunze, 1969; Teele, Klein, Rosner, et al., 1984) but not by others (Brookhouser and Goldgar, 1987; Lous, Fiellau-Nikolajsen, and Jeppesen, 1988; Wright, Sell, McConnell, et al., 1988; Teele, Klein, Chase, et al., 1990). Similarly, children tested with the Reynell Developmental Language Scales have shown significant differences in some studies (Silva, Kirkland, Simpson, et al., 1982; Silva, Chalmers, and Stewart, 1986) but not in others (Rach, Zielhuis, and van den Broek, 1988; Brookhouser and Goldgar, 1987).

Moreover, although statistically significant performance differences can appear between cohort groups, the performances of both groups can fall within the normal ranges established for that test and age range. In such cases, the effect would be described most appropriately as language differences rather than delays. How such differences can affect development in cognitive, behavioral, and speech and language domains is unknown, just as the functional significance of isolated, specific test deficits is unclear. In addition, when test scores are scaled to age norms it is difficult to dissociate deficits from delays, and this problem has not been addressed in children with otitis media with effusion.

young children

No. of controls	Design[1]	Test[2]	Age at study assessment (years)	Effects of otitis media with effusion[3]
13	P,Co	PSI	4	S
0	P,Co	G-F-W	2.5-8	NS
0	P,Co	G-F-W	7	S
0	P,Co	REEL, SICD-R	1-2	S
0	P,Co	SICD-R	1-2	NS 18,24m; S 12m
13	P,Co	SICD-R	4	NS
26	A,Ca	PPVT	8	NS
13	P,Co	Reynell	2-4	NS
18	P,Ca	Reynell	4	NS
0	P,Co	M-Y, BLST, PPVT, CELF	4-6	NS
0	P,Co	PPVT	3	S
		ACQ		S
		VAQ		NS
0	P,Co	PPVT, WUG	7	NS
0	P,Co	PPVT, PLS, REEL, Boone	2-4	NS
0	P,Co	REEL SICD-E	1-2	S
0	P,Co	Paraphrase	5,7	S
		MLU		NS
0	P,Co	SICD-E	1-2	NS 12,24m; S 18m
13	P,Co	Reynell	2-4	S
18	P,Ca	Reynell	2-4	S
0	P,Co	CELF-E, MLU	4-6	NS
0	P,Co	Language sample	7	S
		WUG, Boston		NS
0	P,Co	PLS, REEL, Boone	2-4	NS
0	P,Co	WPPSI	5,7	S
0	P,Co	WISC-R	8	NS
0	P,Co	CBI	8	S
0	P,Co	SCAN	5,7	S

PLS = Zimmerman Preschool Language Scale. PPVT = Peabody Picture Vocabulary Test. PSI = Pediatric Sentence Intelligibility Test. REEL = Receptive-Expressive Emergent Language Scale. Reynell = Reynell Developmental Language Scales. SCAN = Behavioral observation of task-oriented, affective, and social actions. SICD = Sequenced Inventory of Communication Development. VAQ = Verbal Ability Quotient (Zimmerman Preschool Language Scale). WISC-R = Wechsler Intelligence Scales for Children (Revised Versions). WPPSI = Wechsler Preschool on a Primary Scale of Intelligence. WUG = "WUG" Test.

[3] Abbreviations used for effect: NS = not statistically significant. S = significant ($p \leq 0.05$).

Table 2. Evidence on long-term outcomes of otitis media with effusion in

Developmental domain		Reference	No. of subjects
Speech	Receptive	Gravel and Wallace, 1992	10
	Expressive	Roberts, Burchinal, Koch, et al., 1988	55
		Teele, Klein, Chase, et al., 1990	194
Language	Receptive	Friel-Patti, Finitzo-Hieber, Conti, et al., 1982	35
		Friel-Patti and Finitzo, 1990	483
		Gravel and Wallace, 1992	10
		Lous, Fiellau-Nikolajsen, and Jeppesen, 1988	26
		Rach, Zielhuis, and van den Broek, 1988	52
		Rach, Zielhuis, van Baarle, et al., 1991	84
		Roberts, Burchinal, Davis, et al., 1991	63
		Teele, Klein, Rosner, et al., 1984	205
		Teele, Klein, Chase, et al., 1990	194
		Wright, Sell, McConnell, et al., 1988	156
	Expressive	Friel-Patti, Finitzo-Hieber, Conti, et al., 1982	35
		Feagans, Sanyal, Henderson, et al., 1987	44
		Friel-Patti and Finitzo, 1990	483
		Rach, Zielhuis, and van den Broek, 1988	52
		Rach, Zielhuis, van Baarle, et al., 1991	84
		Roberts, Burchinal, Davis, et al., 1991	63
		Teele, Klein, Chase, et al., 1990	194
		Wright, Sell, McConnell, et al., 1988	156
Other	Intelligence	Roberts, Sanyal, Burchinal, et al., 1986	61
		Roberts, Burchinal, Collier, et al., 1989	44
	Behavior	Roberts, Burchinal, Collier, et al., 1989	44
		Feagans, Sanyal, Henderson, et al., 1987	44

[1] Abbreviations used for design: A = ambispective study (data collected by history as well as after enrollment in study). Ca = case control (data from children with the problem paired for comparison with data from children without variable). Co = cohort (group of children studied at different points in time). P = prospective study (data collected after enrollment in study).
[2] Abbreviations used for tests: ACQ = Auditory Comprehension Quotient (Zimmerman Preschool Language Scale). BLST = Bankson Language Screening Test. Boone = Boone Infant Speech and Language Development. Boston = Boston Naming Test. CBI = Classroom Behavior Inventory. CELF = Clinical Evaluation of Language Functions. G-F-W = Goldman-Fristoe-Woodcock Test of Articulation. MLU = Mean Length of Utterance. M-Y = Miller-Yoder Language Comprehension Test.

Some cohort studies reported greater variance within groups than between groups on standardized measures of speech or language (Lous, Fiellau-Nikolajsen, and Jeppesen, 1988), suggesting a complex relationship between developmental delays and otitis media with effusion. The Panel found that, despite documentation of performance deficits in some children who were prone to otitis media with effusion, the available literature fails to provide definitive support for the proposed causal relationship in three principal areas:

- There have been no randomized clinical studies in which otitis media with effusion has been left completely untreated in children with the intention of studying its long-term effects on speech, language, and hearing—a problem influenced as much by ethical considerations as by the scientific method.
- Few studies have measured hearing levels in children, relying instead on frequency or duration of effusion as a predictive variable for developmental outcome.
- There is no consensus on which of the many aspects of speech, language, or learning are affected by early otitis media with effusion; thus, a broad array of test instruments have been used, leading to inconclusive or conflicting results among studies.

Experts theorize that persistent or fluctuating hearing loss produced by middle ear effusion degrades the incoming acoustic speech signal so that incomplete and inaccurate information is available for learning speech and language skills (Roberts, Sanyal, Burchinal, et al., 1986; Teele, Klein, Rosner, et al., 1984; Roberts, Burchinal, Koch, et al., 1988; Friel-Patti and Finitzo, 1990). Among the studies reviewed, however, there was little uniformity in reporting subjects' hearing levels.

Instead of directly documenting hearing, some researchers have used the number of episodes of otitis media with effusion or total number of days with otitis media with effusion within a certain period of time as the independent variable, on the assumption that the presence of otitis media with effusion is an adequate surrogate for the presence of hearing loss (type not specified) (Feagans, Sanyal, Henderson, et al., 1987; Gravel and Wallace, 1992; Rach, Zielhuis, and van den Broek, 1988; Rach, Zielhuis, van Baarle, et al., 1991; Roberts, Burchinal, Koch, et al., 1988; Roberts, Burchinal, Collier, et al., 1989; Roberts, Burchinal, Davis, et al., 1991; Teele, Klein, Rosner, et al., 1984; Teele, Klein, Chase, et al., 1990). Studies using this approach have yielded inconsistent results in both the direction and magnitude of effects.

Other researchers have used click-evoked auditory brainstem responses as an indicator of hearing level (Friel-Patti, Finitzo-Hieber, Conti, et al., 1982; Friel-Patti and Finitzo, 1990). Although threshold estimates for click-evoked auditory brainstem responses are not frequency specific, they more accurately reflect sensitivity in the high-frequency region (1,000 to 4,000 Hz) than in the lower frequencies. Because middle ear effusion

A related issue is whether developmental effects are long-lasting. Evidence that hearing changes associated with otitis media with effusion cause dysfunctions that persist into later childhood despite resolution of the otitis media with effusion and a return to normal hearing would provide a compelling argument for early, decisive intervention for otitis media with effusion. Available evidence, however, does not show a consistent effect of otitis media with effusion on language and/or learning once the disease process and its associated hearing loss have resolved (Wright, Sell, McConnell, et al., 1988; Teele, Klein, Chase, et al., 1990; Teele, Klein, Rosner, et al., 1984; Roberts, Burchinal, Davis, et al., 1991; Roberts, Burchinal, Collier, et al., 1989; Roberts, Burchinal, Koch, et al., 1988; Lous, Fiellau-Nikolajsen, and Jeppesen, 1988; Rach, Zielhuis, and van den Broek, 1988; Gravel and Wallace, 1992; Feagans, Sanyal, Henderson, et al., 1987).

Does Treatment of Otitis Media with Effusion Affect Subsequent Speech and Language Development?

A fundamental assumption underlying the treatment of disease is that the treatment will reduce or eliminate the effects of the disorder. Otitis media with effusion can be treated medically, surgically, and/or by control of environmental risk factors; clearing of the effusion results in restoration of normal hearing levels in almost all cases, although the condition can recur and require further treatment. Both short- and long-term outcomes of treatment are of interest.

The immediate restoration of normal hearing with removal of the middle ear effusion is well documented, and there appear to be few long-term residual effects on hearing sensitivity, barring complications such as cholesteatoma, tympanosclerosis, or chronic tympanic membrane perforation (Wright, Sell, McConnell, et al., 1988).

Long-term developmental outcomes of treated and untreated otitis media with effusion have, however, not been compared in randomized controlled clinical studies. One study (Rach, Zielhuis, van Baarle, et al., 1991) compared verbal comprehension and expression in a sample (n = 52) of preschool children with short-term (3 to 6 months) and long-term (6 months or longer) otitis media with effusion; half were treated with bilateral myringotomy and tubes, and the other half received no treatment. At the end of a 6-month followup, language development was assessed and compared with assessments of age-matched children without otitis media with effusion. The results indicated a trend toward improved language development either by treatment with tubes or by time alone, although improvement after treatment seemed to be slightly faster. An additional finding of the study was that spontaneous improvement in language development occurred more readily in children who had had otitis media with effusion for less than 6 months. Despite a trend toward greater improvement in the treatment groups, there was no statistically significant

difference between the treated and untreated groups on the Reynell Developmental Language Scales test.

Other studies reviewed by the Panel followed otitis-prone children for periods of up to 7 years after the history of otitis media with effusion was established (Roberts, Sanyal, Burchinal, et al., 1986; Feagans, Sanyal, Henderson, et al., 1987; Lous, Fiellau-Nikolajsen, and Jeppesen, 1988; Roberts, Burchinal, Koch, et al., 1988; Roberts, Burchinal, Davis, et al., 1991; Teele, Klein, Chase, et al., 1990). The results of these studies are mixed. Most studies indicated that conventional treatment approaches (such as antibiotic therapy or myringotomy with tubes) were used when effusion was present, but the results were not stratified for treatment or age at intervention. Instead, the outcome measures were temporal variables, such as documented days with effusion. By inference, therefore, most children in the reported samples had been treated; some showed long-term effects on receptive or expressive language, but others did not.

Given What Is Known About Speech and Language Development, Is There a Best Time to Treat Otitis Media with Effusion?

The foundations for auditory-verbal skills are laid and refined largely within the first several years of life, the same years in which the incidence of otitis media with effusion is highest (Feagans, Sanyal, Henderson, et al., 1987). The results of longitudinal studies are in agreement that the more time spent with otitis media with effusion and its related hearing loss during the first 3 years, the greater the probability that speech and language deficits will result (Teele, Klein, Rosner, et al., 1984; Teele, Klein, Chase, et al., 1990; Friel-Patti and Finitzo, 1990; Rach, Zielhuis, and van den Broek, 1988). Some have also found that children who have multiple episodes of otitis media with effusion early in life are likely to continue to have that disease (Teele, Klein, Chase, et al., 1990; Teele, Klein, Rosner, et al., 1984; Rach, Zielhuis, and van den Broek, 1988).

The association between brief periods of mild, fluctuating hearing loss and subsequent development is less clear. There seems to be little long-term effect of otitis media with effusion that appears for the first time after age 3 (Teele, Klein, Rosner, et al., 1984), lending support to the concept of a "critical period" for acquisition of communication skills; during this period, sensory deprivation or attenuation of auditory signals can exert more significant effects than they would later in life. This association appears across all study designs, sample characteristics, and tests used.

Are There Variations in Middle Ear Condition That Would Influence a Management Protocol?

Variations in middle ear status that can influence choice of treatment fall into three categories: those that are unusually severe, carrying a high

risk of additional complications; those that are exceptionally mild or that involve only one ear; and those that occur in children with pre-existing sensory deficits. Complications of disease (such as cholesteatoma, adhesions, and tympanic membrane perforation) are not considered here.

Although mild conductive hearing loss generally accompanies otitis media with effusion, middle ear effusions can be present with minimal effects on hearing. Despite studies that have reported a close association between the persistence of otitis media with effusion and speech and language development (Teele, Klein, Rosner, et al., 1984; Teele, Klein, Chase, et al., 1990; Friel-Patti and Finitzo, 1990; Rach, Zielhuis, and van den Broek, 1988), there is no evidence that when hearing remains "normal" there is any effect of otitis media with effusion per se on speech and language. There is no agreement, however, as to the minimal hearing sensitivity necessary for infants and young children to complete the complex process of developing speech and language successfully. In the absence of such a standard, when hearing is within normal limits (defined as less than 20 decibels hearing threshold level) in at least one ear, the Panel recommends against bilateral myringotomy with tubes.

A related problem is seen in the case of persistent unilateral otitis media with effusion. Some have suggested that hearing asymmetry plays a significant role in the development of speech/language delays or disorders (Roberts, Burchinal, Koch, et al., 1988). In about two-thirds of cases (Casselbrant, Brostoff, Cantekin, et al., 1985) otitis media with effusion occurs bilaterally, although the extent of middle ear abnormality—and with it, hearing—can vary between ears. Most studies considered by the Panel either did not track unilateral versus bilateral otitis media with effusion or did not stratify the study samples on that basis when analyzing results. Unilateral hearing loss is known to interfere with normal localization of sound in space and in auditory figure-ground discrimination (Oyler, Oyler, and Matkin, 1987). However, the effects of the typical mild to moderate hearing loss associated with otitis media with effusion on these functions have not been well studied. Within the past 5 years, some evidence has appeared for effects of unilateral and bilateral hearing impairment on certain tests of central auditory function, such as auditory brainstem response recording and the binaural masking level difference test (Hall and Grose, 1993; Pillsbury, Grose, and Hall, 1991). Although the results of these studies are provocative, the effects measured were small, and it is not clear what significance the findings have with regard to the acquisition and refinement of speech and language skills in younger children.

Two conditions merit special consideration in management decisions for otitis media with effusion, although they are beyond the scope of this guideline: (1) when the otitis media with effusion occurs in the only- or better-hearing ear, as with congenital atresia; and (2) when the otitis media with effusion occurs in a child with a known sensorineural hearing loss or severe visual or mental deficit. In each of these circumstances, the impact of even a mild conductive hearing loss can be substantially greater to the

child attempting to learn speech and language skills without the full complement of sensory abilities. When overlaid on a pre-existing sensorineural loss, a conductive impairment reduces the child's ability to use hearing aids and assistive listening devices to acquire auditory-verbal communication skills.

In summary, the Panel found that rigorous, methodologically sound research does not adequately support or refute the theory that untreated otitis media with effusion results in speech/language delays or deficits. Conflicting findings among studies can be accounted for in several ways: limitations in the research designs, lack of uniformity of test instrument selection, lack of definition of hearing status, and interactions between otitis media with effusion and other risk factors (Roberts, Burchinal, Davis, et al., 1991).

4 Guideline: Diagnosis and Hearing Evaluation

In the diagnosis of any health problem, the first step is to obtain a thorough medical history. The history for a child suspected of otitis media with effusion should include date of onset of signs or symptoms of middle ear inflammation, previous treatments (nonprescription as well as prescribed medications and treatments), and the degree of compliance with treatment regimens. The history might also include assessment of environmental risk factors shown by epidemiologic studies to be related to otitis media with effusion, especially infant feeding practices, passive smoking, and child-care facility placement (see Chapter 5).

The general physical examination of a child in whom otitis media with effusion is suspected should include an assessment of growth and development and whether an infectious disease is present. Examination of the head and neck is also crucial in identifying conditions associated with or predisposing to otitis media with effusion, such as nasal obstruction or craniofacial anomalies affecting the middle ear (cleft palate, for example) (Bluestone and Klein, 1990).

Otitis media with effusion can be diagnosed definitively only when the presence of fluid in the middle ear is confirmed. In the best-designed clinical research studies of diagnostic methods for otitis media with effusion, the diagnostic method to be evaluated (such as pneumatic otoscopy or tympanometry) is implemented and followed immediately by myringotomy (performed in the context of an indicated surgical procedure, such as the insertion of ventilation tubes) to document the effusion. Without myringotomy, diagnostic methods in common use provide only indirect evidence for the presence of fluid.

In conducting the literature review for diagnostic tests, the Panel searched for studies in which the selection criteria, patient population, and diagnostic methods were clearly described; patients' medical histories were consistent with otitis media with effusion as defined by the Panel; and the presence of effusion was validated by performance of myringotomy by a surgeon who was blinded to results from the initial diagnostic test. An important methodological issue is that the true sensitivity, specificity, and negative predictive value of diagnostic tests for the presence of middle ear effusion are not known, because myringotomy has not been performed in a matched group of children in whom otitis media with effusion is not suspected. The numbers of subjects with and without effusion who have a negative initial test must be known in order to calculate a test's sensitivity, specificity, and negative predictive value (Table 3).

Because ethical considerations preclude a study involving myringotomy in healthy children with apparently normal ears, and limited

Table 3. Definitions of sensitivity, specificity, positive predictive value, and negative predictive value of tests to diagnose middle ear effusion, validated by findings at myringotomy

Diagnostic test result	Findings at myringotomy	
	Percentage with effusion	Percentage with no effusion
Abnormal test result	*a*	*b*
Normal test result	*c*	*d*

$$\text{Sensitivity} = \frac{a}{a + c} = \frac{\text{number of true positive test results}}{\text{number of true positive + number of false negative test results}}$$

$$\text{Specificity} = \frac{d}{b + d} = \frac{\text{number of true negative test results}}{\text{number of false positive + number of true negative test results}}$$

$$\text{Positive predictive value} = \frac{a}{a + b}$$

$$\text{Negative predictive value} = \frac{d}{c + d}$$

data are available that correlate a negative screening test with effusion when otitis media with effusion is suspected on other grounds, the only valid test measure available from published research is the predictive value of a positive test: the likelihood that an effusion is present if the initial diagnostic test is positive. On this basis, the Panel searched for literature describing the relationship of otoscopy, pneumatic otoscopy, tympanometry, acoustic reflectometry, tuning fork tests, and hearing evaluation with middle ear effusion as determined by myringotomy.

Otoscopy and Pneumatic Otoscopy

Recommendation: The diagnostic evaluation of suspected otitis media with effusion should include pneumatic otoscopy. Otoscopy alone (without the use of the pneumatic otoscope to test tympanic membrane mobility) is not recommended. *[Strong recommendation based on limited scientific evidence and strong Panel consensus.]*

The history and physical examination provide vital clues to the presence of otitis media with effusion. However, confirming the diagnosis requires establishing the presence of a middle ear effusion. The principles and usefulness of pneumatic otoscopy for detecting effusion were first reported by Siegle more than a century ago and popularized by Politzer (1909). Pneumatic otoscopy is a two-step procedure. In the first step, the clinician inspects the ear canal and eardrum visually, using a light source and magnification (otoscopy). In the second step, the clinician creates a seal in the ear canal and applies very slight positive and then negative

pressure while watching the tympanic membrane to evaluate its mobility (pneumatic otoscopy).

On otoscopy, the clinician assesses tympanic membrane color, translucency, and resting position (retracted, neutral). The normal tympanic membrane is translucent, with a ground-glass appearance. Usually pearly grey, even a healthy tympanic membrane turns red when the patient cries. Although otoscopes are ubiquitous in clinical settings, few data are available correlating otoscopic findings with the presence of middle ear effusion, and few studies have provided any information about the criteria that suggest effusion. In one study, Finnish researchers sought to correlate tympanic membrane appearance with effusion in children with acute otitis media and otitis media with effusion; the predictive values of visible eardrum characteristics ranged widely (Karma, Penttila, Sipila, et al., 1989).

The pneumatic otoscope, which allows the examiner to observe movement of the tympanic membrane directly, has been widely credited as an advance over otoscopy alone, because pneumatic otoscopy can suggest the presence of effusion even when the appearance of the eardrum gives no indication of middle ear pathology. For this test, crisp movement of the tympanic membrane with slight application of pressure is normal. Thickening of the eardrum causes it to be less mobile. If the tympanic membrane does not move perceptibly with applications of slight positive or negative pressure, a middle ear effusion is highly likely. The examiner should note, however, that almost any eardrum will move if enough pressure is applied. Sometimes application of pressure will reveal an air-fluid level behind the tympanic membrane, and this is diagnostic of a middle ear effusion (Bluestone and Klein, 1990).

When employed under rigorously controlled conditions (i.e., when results of the procedure performed by a clinician who was validated using a prescribed protocol are compared with results of myringotomy performed by another clinician immediately after the procedure), pneumatic otoscopy was found in one study to have a sensitivity of 85 to 90 percent and specificity of 70 to 79 percent (Kaleida and Stool, 1992). In this study, the clinical indications for myringotomy were not clearly described; however, the prevalence of middle ear effusion in the study population must be assumed to be high.

In another study comparing findings at pneumatic otoscopy and at myringotomy, positive and negative predictive values of pneumatic otoscopy for middle ear effusion were found to be 91 percent and 84 percent, respectively (Toner and Mains, 1990). Because, as just discussed, the expectation of middle ear effusion must be very high in a study population to justify myringotomy in every child, the prevalence of otitis media with effusion was probably higher than would be found in a typical clinical setting. Thus, in a typical clinical setting, the positive predictive value of pneumatic otoscopy would be lower and the negative predictive value higher than in the research setting. Another factor that

would tend to decrease the positive predictive value and increase the negative predictive value of this test in clinical settings is the lack of calibration of test results against findings at myringotomy.

Tympanometry

Option: Tympanometry may be used as a confirmatory test for otitis media with effusion. *[Option based on limited scientific evidence and expert opinion.]*

Many studies have been conducted to identify correlations between tympanometric findings and the presence of middle ear effusion at myringotomy. Problems have arisen with application of findings to clinical practice, however, because of variations in the way tympanograms have been categorized and the absence of data that would allow calculation of the true sensitivity, specificity, and negative predictive values in typical practice populations.

Early research into the association of tympanometric curves with conditions in the middle ear classified tympanometry results into four or more categories (Jerger, 1970; Bluestone, Beery, and Paradise, 1973; Paradise, Smith, and Bluestone, 1976; Shurin, Pelton, and Finkelstein, 1977; Cantekin, Beery, and Bluestone, 1977). Later research classified tympanogram curves into three categories: Type A (peaked, normal middle ear pressure), Type B (flat), and Type C (peaked, negative middle ear pressure, sometimes further divided into two types according to degree of negative pressure) (Jerger, Anthony, Jerger, et al., 1974; Tos, Poulsen, and Borch, 1978; Fiellau-Nikolajsen, 1980a,b).

The most recent research has further collapsed the three types into two clinically useful categories: normal (Types A, C, and D, peaked) and abnormal (Type B, flat) (Toner and Mains, 1990; Dempster and MacKenzie, 1991; Babonis, Weir, and Kelly, 1991). In the following discussion, the simpler two-category classification is used. Tables in the original reports that used more complex classification schemes were collapsed into the simpler system to fit diagnostic information from the early studies into a format consistent with current practice.

The positive predictive value for middle ear effusion of a flat (Type B) tympanogram (i.e., the likelihood that an effusion is present if the tympanogram is abnormal) has been found to be between 49 and 99 percent (Fiellau-Nikolajsen, 1980a,b; Orchik, Morff, and Dunn, 1980; Ben-David, Podoshin, and Fradis, 1981; Babonis, Weir, and Kelly, 1991). In a few studies, tympanometry was performed in children who were scheduled for myringotomy indicated for reasons other than tympanometric findings. A negative predictive value for tympanometry can be estimated from the few patients in these studies who had normal tympanogram results and who underwent myringotomy. In this highly selected population, the negative predictive value of a normal tympanogram (i.e.,

the likelihood that no effusion is present when the tympanogram is normal) was estimated to be between 64 and 93 percent (Fiellau-Nikolajsen, 1980a,b; Orchik, Morff, and Dunn, 1980; Ben-David, Podoshin, and Fradis, 1981).

Since tympanometry became clinically available, clinicians have sought to use this diagnostic tool as a screening test for otitis media with effusion (Paradise, Smith, and Bluestone, 1976). Indeed, it has been used as a screening test (without myringotomy for confirmation) by many researchers in the United States and Europe. Longitudinal cohort studies of children followed with tympanometry have provided some of the best data available regarding the natural history of otitis media with effusion. In particular, such studies have shown that otitis media with effusion resolves without treatment in most cases (Tos, Poulsen, and Borch, 1978; Fiellau-Nikolajsen, 1980a,b; Roland, Finitzo, Friel-Patti, et al., 1989).

Although several articles reviewed by the Panel mention in passing the possibility of using tympanometry as a surrogate for hearing evaluation, the Panel did not find direct evidence in support of this strategy. The clinical utility of tympanometry is limited to measuring the mobility of the tympanic membrane and ossicles and providing an estimate of middle ear pressure. As such, it is neither an appropriate nor a reliable predictor of hearing impairment, except in the most nonspecific sense as a risk marker for the hearing impairment associated with middle ear pathology. Indeed, the positive predictive value for hearing loss of an abnormal tympanogram has been reported to be as low as 49 percent (Dempster and MacKenzie, 1991). Clearly, with a positive predictive value for hearing loss of only 49 percent, tympanometry cannot be used in place of hearing evaluation—half the patients with abnormal tympanometric results could have normal hearing, and theoretically, half with normal results could have abnormal hearing. The negative predictive value, however, is 98 percent (Dempster and MacKenzie, 1991), reflecting the lower prevalence of sensorineural hearing impairment. That is, few children with normal tympanograms have hearing impairment, although those with pure sensorineural pathology and no middle ear involvement do have normal tympanograms. The American Academy of Pediatrics Committee on School Health (1987) specifically recommends against use of tympanometry as the primary screening test for hearing impairment.

Combination of Tympanometry and Pneumatic Otoscopy

Although pneumatic otoscopy and tympanometry essentially measure the same thing—tympanic membrane mobility—the strengths of one test can offset the weaknesses of the other. For example, tympanometry gives a quantitative measure of tympanic membrane mobility, whereas pneumatic otoscopy gives only a qualitative measure of this variable. In addition, a

false-positive tympanometry result (abnormal tympanogram in the absence of effusion) can be caused by impacted cerumen, a foreign body, tympanic membrane perforation, medial canal stenosis, or improper placement of the instrument tip on the canal wall; performing pneumatic otoscopy before or after tympanometry provides information about ear anatomy and tympanic membrane mobility critical to interpretation of tympanometry results. Accordingly, the Panel recommends pneumatic otoscopy as the primary diagnostic test. Tympanometry may be used as a confirmatory test.

Because of the complementary nature of these two tests, researchers have constructed algorithms for the diagnosis of otitis media with effusion based on combined tympanometric and pneumatic otoscopic findings. Algorithms in widest use include those proposed by Cantekin (1983) and updated by Brostoff and Cantekin (1988). The Panel did not find direct evidence linking the outcome of these algorithms to the presence or absence of middle ear effusion. Le, Daly, Lindgren, et al. (1992) proposed an algorithm in which results of diagnostic testing are validated against findings at myringotomy. None of the research algorithms combining pneumatic otoscopy and tympanometry has been tested for usefulness in clinical practice.

Acoustic Reflectometry

No Recommendation: No recommendation is made regarding the use of acoustic reflectometry as a screening or diagnostic test for otitis media with effusion.

Acoustic reflectometry is a relatively new technique in which a tone sweep is presented to the patient's ear canal and the reflected sound pressure is recorded in decibels. The initial report of this technique stated that in one population of children, in most of whom middle ear disease had been diagnosed by some other method, acoustic reflectometry had high (86 percent) sensitivity and high (76 percent) specificity for otitis media with effusion when correlated with findings at myringotomy (Teele and Teele, 1984). Even higher sensitivity (98.7 percent) and specificity (94.5 percent) were obtained when reflectivity and angle were optimized and tympanometry was used as the reference standard (Combs, 1991). Other studies have not yielded consistent results, with sensitivity of this test ranging from 80 to 87 percent and specificity ranging from only 54 to 70 percent (Lampe, Weir, Spier, et al., 1985; Avery, Gates, and Prihoda, 1986; Babonis, Weir, and Kelly, 1991). One of these studies examined the receiver-operator characteristic of acoustic reflectometry and found no acceptable breakpoint dividing a high probability of effusion from a low probability of effusion; this study did, however, suggest that the absolute value can be less important than documenting a change in a single individual (Avery, Gates, and Prihoda, 1986).

The Panel judged the evidence in support of acoustic reflectometry to be insufficient to make a recommendation regarding use of this test in screening for or diagnosis of otitis media with effusion.

Tuning Fork Tests

No Recommendation: No recommendation is made regarding the use of tuning fork tests in screening for or diagnosis of otitis media with effusion, except to note that they are inappropriate in the youngest children.

The Panel recognized that many experts use tuning fork tests to evaluate hearing and as an indirect means to diagnose otitis media with effusion by assessing conductive hearing loss. However, the Panel found no reports of studies that used other tests as standards against which to judge the sensitivity, specificity, and predictive value of tuning fork tests to identify otitis media with effusion in children. Furthermore, tuning fork tests are not reliable or even appropriate for use in the youngest children covered by this Guideline. A number of methods to test directly for the presence of a middle ear effusion, including pneumatic otoscopy and tympanometry, have been discussed, and better methods are available to assess hearing (see next section).

Hearing Evaluation

Option: Hearing evaluation may be performed before otitis media with effusion has been present for a total of 3 months. *[Option based on insufficient evidence.]*

Recommendation: Hearing evaluation is recommended for a child who has had bilateral otitis media with effusion for a total of 3 months. *[Recommendation based on limited scientific evidence and expert opinion.]*

A change in hearing threshold is both a clinical outcome and a possible indicator of the presence of otitis media with effusion. Tests that may be used to evaluate hearing (listed in approximate order from those requiring greatest language and communication skills from the patient to those requiring the least skills) include: (1) pure tone threshold audiometry measuring both air and bone conduction, (2) speech reception threshold audiometry, (3) speech awareness threshold audiometry, (4) behavioral observation audiometry, and (5) auditory brainstem response recording and evaluation.

Children who fail hearing screening tests are usually referred to a physician, but the Panel found no direct evidence to estimate the proportion of these children who have otitis media with effusion. The corollary linkage between otitis media with effusion and hearing is better understood: several studies have documented hearing impairment in

children with otitis media with effusion diagnosed by tympanometry and pneumatic otoscopy (Fria, Cantekin, and Eichler, 1985; Friel-Patti and Finitzo, 1990; Dempster and MacKenzie, 1991). Otitis media with effusion is not always associated with hearing impairment, however. For example, one well-designed study of language learning and hearing in very young children with otitis media with effusion found a correlation of only 0.44 between days with effusion and average hearing over a 12-month period (Friel-Patti and Finitzo, 1990). Days of effusion accounted for less than 20 percent of the observed variation in hearing in this study.

The Panel recognizes that none of the hearing tests found to be effective (with the exception of pure-tone threshold audiometry, which is appropriate only for older children) is routinely available in many primary care settings, especially in rural areas. Furthermore, the Panel recognizes that there are difficulties with the validity, availability, and cost of hearing testing in the youngest children. Nevertheless, for otherwise healthy children age 1 through 3 years, the Panel recommends hearing evaluation after otitis media with effusion has been present bilaterally for 3 months, because of the strong belief that the placement of tympanostomy tubes is not indicated when otitis media with effusion is unaccompanied by bilateral hearing impairment (defined as 20 decibels hearing threshold level or worse in both ears).

Methods used to determine the child's hearing acuity will vary depending on resources available in the community and the child's willingness and ability to participate in testing. Optimally, air- and bone-conduction thresholds can be established for 500, 1,000, 2,000, and 4,000 Hz, and an air-conduction pure tone average can be calculated. This result can then be verified by obtaining a measure of speech sensitivity. Determinations of speech reception threshold and speech awareness threshold are less precise but still acceptable measures of hearing acuity. In the event that facilities or resources are not readily available or the child is unable to cooperate in such testing, the health care provider should use his/her best judgment as to the adequacy of the child's hearing. In these cases, the health care provider should take into consideration whether the child is achieving the appropriate developmental milestones for communication skills.

5 Guideline: Control of Environmental Risk Factors

The Panel conducted a literature review of environmental risk factors for otitis media with effusion, with the goal of identifying preventive interventions for this condition. Reports were found of research into the association of infant feeding practices, passive smoking, and child-care facility placement with the occurrence of otitis media with effusion, with or without other types of otitis media. None of the studies reported, however, was designed to test the direction or strength of the linkage between these environmental factors and the incidence or natural history of otitis media with effusion, and the articles found were not subjected to the same level of scrutiny by the entire Panel that was accorded articles reporting diagnostic and treatment interventions. The remainder of this chapter describes the findings of the literature review. These findings did not provide information regarding whether intervening to decrease environmental risk factors would make a clinically important difference in the care of otherwise healthy young children with otitis media with effusion.

Option: Parents should be encouraged to control environmental risk factors. *[Option based on limited scientific evidence and strong Panel consensus.]*

Infant Feeding Practices

The Panel reviewed literature linking early infant feeding practices to later otitis media, even though the target patient for Guideline development was past the age when a change in infant feeding practices would have much effect in preventing middle ear effusion.

Some studies of breast-feeding versus bottle-feeding showed a several-fold increase in otitis media in bottle-fed compared to breast-fed infants (Saarinen, 1982; Cunningham, 1979; Chandra, 1979; Duncan, Ey, Holberg, et al., 1993; Teele, Klein, and Rosner, 1989; Alho, Koivu, Hartikainen-Sorri, et al., 1990), suggesting that breast-feeding may provide some protection against otitis media. In addition, Eskimo and Inuit studies point to a link between bottle-feeding and an increased incidence of chronic otitis media (Timmermans and Gerson, 1980).

The available literature on infant feeding practices and otitis media is descriptive and focuses on acute otitis media, not on otitis media with effusion. Thus, although studies suggest that bottle-fed infants are two or three times more likely to have episodes of acute otitis media during the first year of life, the proportion who develop otitis media with effusion as a consequence is unknown. Furthermore, the direction of the linkage

cannot be determined from available research. For example, perhaps infants with acute otitis media are weaned to the bottle earlier, giving the appearance that bottle-feeding is correlated with acute otitis media when in fact the acute otitis media "caused" bottle-feeding. Finally, the linkage is not firm: several studies have failed to find an association between feeding practices and otitis media (Tainio, Savilahti, Salmenpera, et al., 1988; Paine and Coble, 1982).

Some experts believe that propping a feeding bottle is a practice that may promote the occurrence of otitis media with effusion. The hypothesis is that when a bottle is propped in place, fluid is forced under pressure into the oral cavity, leading to reflux into the middle ear (Bluestone and Klein, 1988). The Panel could locate no research related to bottle propping and otitis media with effusion.

In summary, available research linking infant feeding practices to otitis media with effusion is provocative, but inconclusive. If a causal link is eventually demonstrated, better parent education about infant feeding practices might lead to fewer episodes of otitis media with effusion in later years. By the time a child reaches the age considered in this Guideline, however, the issue is only of historical interest.

Passive Smoking

Evidence that passive smoking may be related to otitis media with effusion has been reported only during the past decade and is limited. Kraemer, Richardson, Weiss, et al. (1983) documented a relative risk of 2.8 for children in households with two or more smokers in an early case-control study. Two other independent early studies documented odds ratios of 1.6 for parental smoking and abnormal tympanometry results or for the risk of surgery for glue ear (Iverson, Birch, Lundqvist, et al., 1985; Black, 1985). In a case-control study, 57 percent of children with otitis media with effusion (cases) had at least one parent who smoked, compared with 39 percent of children without otitis media with effusion (controls) (Hinton, 1989). A more recent case-control study of similar design, however, failed to find the same association (Rowe-Jones and Brockbank, 1992). In a followup study of children with severe chronic otitis media with effusion (glue ear), parental smoking delayed the time to resolution regardless of treatment chosen (Maw and Bawden, 1993).

Two studies found a correlation between higher levels of serum cotinine (a marker for nicotine) and otitis media with effusion. In a randomly chosen sample of Edinburgh primary school children, a direct correlation was found between serum cotinine levels and abnormal tympanograms (Strachan, Jarvis, and Feyerabend, 1989). Another study found a 38 percent higher rate of new episodes of otitis media during the first 3 years of life in children with high levels compared with children with low or undetectable levels of serum cotinine (Etzel, Pattishall, Haley, et al., 1992); the authors estimated that approximately 8 percent of cases of

otitis media with effusion and 18 percent of the days with otitis media with effusion may be attributable to passive smoking.

Overall, studies have shown a moderate association between passive smoking and otitis media with effusion. Although proof is lacking that cessation of passive smoking will help prevent otitis media with effusion, the association of passive smoking with otitis media with effusion is consistent across a variety of study designs and is biologically plausible. Thus, the possibility that freedom from passive smoking will decrease a child's risk for and time with otitis media with effusion should be added to the many other reasons for parents and child-care providers to stop smoking.

Child Care

Descriptive research conducted during the past 15 years consistently shows a relationship between otitis media with effusion and child care in group facilities (child-care facilities). This relationship has been observed in the context of research demonstrating an association between many common childhood infections and child-care facility attendance.

One of the earliest population-based studies found a three- to fourfold increase in the prevalence of secretory otitis media in children attending child-care facilities, regardless of season of year (Fiellau-Nikolajsen, 1979). An early Danish study that explored the relationship between otitis media with effusion and a number of factors in the child's history found abnormal tympanograms in 76 percent of children cared for in public child-care facilities versus 69 percent of children cared for at home, a difference that was not statistically significant and not adjusted for other factors (Sorenson, Holm-Jensen, and Tos, 1981). A British case-control study found a relative risk of between 1.47 and 2.00, depending on the control group selected, for otitis media with effusion in young children, adjusted for household smoking, parental working, family history, residence, and type of heating system (Black, 1985). A cohort study in Denmark of children cared for at home or in child-care facilities found that the common cold was followed by secretory otitis media in 56 percent of 1-year-old children cared for at home versus 83 percent cared for in child-care facilities, but that the rate was 20 percent in both groups by the time children attained the age of 5 years (Birch and Elbrond, 1987).

A study of 386 children in Minnesota with recurrent acute otitis media and otitis media with effusion at entry found an odds ratio of 1.2 for child-care facility placement and otitis media with effusion after adjustment for age, age at first episode of otitis, season of birth and enrollment, and antibiotic prophylaxis (Daly, Giebink, Le, et al., 1988). Two population-based European studies found odds ratios of 1.7 and 1.8 for otitis media with effusion in children attending child-care facilities, but variably adjusted for confounding factors (Zielhuis, Heuvelmans-Heinen, Rach, et al., 1989; Alho, Koivu, Hartikainen-Sorri, et al., 1990). A similarly

designed Swedish cohort study of 1,306 children found a slightly higher relative risk of 2.6 (Rasmussen, 1993).

All of the studies surveyed suffered from one or more design flaws. For example, many studies were retrospective, and some of the cohort studies were conducted on children already known to be at high risk of otitis media with effusion. More importantly, the cause of otitis media with effusion is multifactorial, and none of the studies adequately adjusted for all known confounding factors.

Despite their shortcomings, these studies point consistently to an association between child-care facility attendance and otitis media with effusion. The relative risks are modest (less than 2.0), but potentially very important given the size of the population base. Furthermore, data recently reported from a cohort study of 2,512 newborns followed for 2 years suggest that removing a child from the group child-care environment might lead to a lower incidence of acute otitis media (Alho, Kilkku, Oja, et al., 1993). More research is needed, however, to establish whether removing the child from a group child-care facility prevents otitis media with effusion, or speeds its resolution.

6 Guideline: Pharmaceutical Therapies

Many pharmaceutical agents have been used to treat otitis media with effusion. The Panel examined evidence for the efficacy in resolving otitis media with effusion, and the adverse effects of, antibiotic agents, adrenocorticosteroid medications, antihistamine and/or decongestant preparations, and combinations of these pharmaceutical agents. The Panel did not examine the efficacy of antibiotics in the prevention of acute otitis media ("prophylaxis") during an episode of otitis media with effusion.

Antibiotic Therapy

Option: The use of antibiotic agents is one option for the treatment of a child with otitis media with effusion. *[Based on limited and inconsistent scientific evidence and Panel consensus.]*

Meta-analysis for Guideline development showed a 14 percent increase in the probability that otitis media with effusion would resolve when antibiotic therapy was given versus no treatment (Table 1). When this small improvement in resolution of otitis media with effusion is weighed against the side effects and cost of antibiotic therapy, antibiotic therapy may not be preferable to observation in management of otitis media with effusion in the otherwise healthy young child with no craniofacial or neurologic abnormalities or sensory deficits. To assist in making choices for management of otitis media with effusion, health care providers need to inform parents fully as to the side effects and costs of antibiotic therapy, as well as the benefits and harms of other options for care.

Efficacy of Antibiotics

Antibiotic medications have been considered for treatment of otitis media with effusion because studies have shown that in 27 to 50 percent of cases, middle ear aspirates from children with otitis media with effusion contain bacteria or provide a medium for bacterial pathogens to grow (Liu, Lang, Lim, et al., 1976; Kokko and Tauno, 1976; Sundberg, 1984; Teele, Healy, and Tally, 1980). However, the existence of bacteria in middle ear aspirates is not proof that the pathogens are causing the effusion or that antibiotic therapy will help resolve the effusion. To explore the role that antibiotic therapy might play in managing otitis media with effusion, the Panel examined the literature on the effectiveness of this therapy in clinical situations.

The literature search identified 18 reports of controlled studies (or reanalyses of controlled study data) and 2 published meta-analyses (Rosenfield and Post, 1992; Williams, Chalmers, Stange, et al., 1993) of antibiotic therapy for otitis media with effusion (Table 4). The two

Table 4. Studies considered for inclusion in Guideline meta-analysis of

Authors	Treatment groups
Cantekin, McGuire, and Griffith, 1991 (analysis of data reported by Mandel, Rockette, Bluestone, et al., 1987)	Amoxicillin 40 mg/kg/day + decongestant/antihistamine / Amoxicillin alone / Placebo
	Same as above
	Same as above
Chan, Mandel, Rockette, et al., 1988	Augmentin / Amoxicillin 40 mg/kg/day Amoxicillin each group
	Same as above
Corwin, Weiner, and Daniels, 1986	Erythromycin 50 mg/kg/day + Sulfisoxazole 150 mg/kg/day 10 days / No treatment
Daly, Giebink, Batalden, et al., 1991	Trimethoprim 8 mg/kg/day + Sulfamethoxazole 40 mg/kg/day / Placebo
deCastro, Jaeger, Martin, et al., 1982	Sulfisoxazole 50 mg/kg/day / Placebo
	Same as above
	Same as above
Ernstson and Anari, 1985	Cefaclor 20 mg/kg/day 10 days / No treatment
Giebink, Batalden, Le, et al., 1990	Trimethoprim-Sulfamethoxazole 40 mg/kg/day / No treatment
Healy, 1984	Trimethoprim 8 mg/kg/day + Sulfamethoxazole 40 mg/kg/day / No treatment
Mandel, Rockette, Bluestone, et al., 1987	Amoxicillin 40 mg/kg/day + decongestant/antihistamine / Amoxicillin alone / Placebo

antibiotics for otitis media with effusion or included in other meta-analyses

No. of patients per group	Outcome measure and time of measurement	No. of patients cured per group
155 / 155 / 150	Otoscopy 4 weeks	52 / 49 / 25
155 / 154 / 150	Tympanometry 4 weeks	26 / 25 / 13
140 / 134 / 131	Audiometry 4 weeks	38 / 46 / 43
56 / 50	Algorithm 10 days	29 / 16
52 / 45	Algorithm 4 weeks	26 / 23
66 / 65	Otoscopy with tympanometric confirmation 1 month	33 / 22
21 / 21	Pneumatic otoscopy and tympanometry 2 weeks	5 / 2
15 / 15	Otoscopy 1 month	11 / 2
15 / 15	Audiometry 1 month	10 / 1
15 / 15	Tympanometry 1 month	5 / 0
46 / 45	Otoscopy and tympanometry (A and C1) and normal hearing = cured 2-5 weeks	24 / 5
20 / 19	Algorithm (sensitivity 0.87, specificity 0.74) 4 weeks	10 / 6
96 / 93	Positive results on otoscopy and type B or C tympanogram = effusion present 4 weeks	56 / 6
158 / 160 / 156	Algorithm 4 weeks	50 / 46 / 22

Table 4 (continued)

Authors	Treatment groups
Mandel, Rockette, Paradise, et al., 1991	Erythromycin 50 mg/kg/day + Sulfisoxazole 150 mg/kg/day / Cefaclor 40 mg/kg/day / Amoxicillin 40 mg/kg/day / Placebo
	Same as above
Marks, Mills, and Shaheen, 1981	Cotrimoxazole / Dimetapp
Moller and Dingser, 1990	Erythromycin 50 mg/kg/day 14 days / Placebo
Podoshin, Fradis, Ben-David, et al., 1990	Amoxicillin 50 mg/kg/day / Placebo
	Same as above
Schloss, Dempsey, Rishikof, et al., 1988	Erythromycin 50 mg/kg/day + Sulfisoxazole / Placebo Tympanocentesis on all patients
Schwartz and Rodriguez, 1982	Trimethoprim-Sulfamethoxazole 4 mg/kg/day / Placebo
Sundberg, Eden, Ernstson, et al., 1981	Erythromycin 40-60 mg/kg/day / No treatment
Thomsen, Sederberg-Olsen, Balle, et al., 1989[1]	Augmentin 5 mL-7.5 mL three times a day / Placebo
Varsano, Volovitz, and Mimouni, 1985	Sulfisoxazole 250-500 mg two times a day / Placebo

[1] The data reported in this study were the subject of a letter to the editor (Cantekin EI. Antibiotics for secretory otitis media. Arch Otolaryngol Head Neck Surg 1990 May;16(5):626-8).

published meta-analyses differed in the studies they included and how the studies were rated, but both concluded that antibiotics have a small but significantly positive effect on resolution of otitis media with effusion. The Panel was also provided an unpublished meta-analysis by Cantekin and McGuire.

No. of patients per group	Outcome measure and time of measurement	No. of patients cured per group
80 / 77 / 79 / 78	Algorithm 2 weeks	17 / 17 / 25 / 11
60 / 52 / 54 / 55	Algorithm 4 weeks	20 / 26 / 23 / 20
25 / 26	Flat tympanogram to peaked or 20-decibel audiometric improvement = cured 4-6 weeks	16 / 7
69 / 72	"Air filled" and tympanogram 1 month	12 / 11
49 / 37	Tympanometry 2 months	20 / 5
49 / 37	Audiometry 2 months	29 / 21
25/27	Pneumatic otoscopy, tympanometry, audiometry 2 weeks	6 / 8
33 / 36	Pneumatic otoscopy and tympanometry 42 days	29 / 32
47 / 72	Otoscopy with some tympanometry, myringotomy, and audiometry 2-5 weeks	21 / 11
111 / 110	Tympanometry (A, C1) = cured 1 month	69 / 34
19 / 16	Pneumatic otoscopy, 5 weeks	10 / 8

The Panel examined antibiotic therapy data particularly carefully because of a conflict in the literature concerning interpretation of data from a study conducted at the Otitis Media Research Center at the University of Pittsburgh. The initial published analysis of these data was challenged by one of the investigators, who published a different interpretation of the

data (Cantekin, McGuire, and Griffith, 1991). Because the Panel included individuals who were affiliated with (by having trained or been employed at) the University of Pittsburgh, and because the University of Pittsburgh was the subcontractor for the Guideline literature review, the Panel took several steps to preserve its impartiality in evaluating evidence regarding antibiotic therapy for otitis media with effusion:

- Members of the Panel who were affiliated with the University of Pittsburgh recused themselves from discussions of antibiotic therapy for otitis media with effusion.
- A subcommittee of the Panel was formed to evaluate the conflicting published and unpublished meta-analyses and to provide written recommendations for management of these reports in development of the Guideline (the complete subcommittee report is contained in the *Guideline Technical Report*).
- All articles originating at the University of Pittsburgh were reviewed independently by an individual not affiliated with the University of Pittsburgh.
- An independent analyst reviewed studies of antibiotic therapy for otitis media with effusion and also reviewed the results of the Panel's analysis of this topic.
- Evaluations of material to be included in this section of the Guideline were performed by individuals not affiliated with the University of Pittsburgh.

The Panel elected to examine all 18 randomized studies and reanalyses of antibiotic therapy for otitis media with effusion, but to concentrate on the 10 studies in which investigators appeared to be effectively blinded to the therapy provided to patients (Table 5, meta-analysis number 8). Antibiotic medications evaluated in these 10 studies included amoxicillin with and without clavulanate potassium, cefaclor, erythromycin with and without sulfisoxazole, sulfisoxazole, and the combination of trimethoprim and sulfamethoxazole.

In addition to evaluating a variety of antibiotic agents, these 10 studies used a variety of methods to diagnose the condition and to assess the effectiveness of the medications in treating otitis media with effusion. Methods to diagnose otitis media with effusion in these studies included tympanometry, otoscopy, hearing evaluation, or a combination of these modalities. Investigators in these 10 studies measured outcomes at various times, from a minimum of 10 days to a maximum of 2 months after the start of antibiotic treatment of otitis media with effusion. These differences in study design made meta-analysis of the data challenging.

In developing this Guideline, the Panel performed eight different meta-analyses, each one using a different subset of the available data. The subsets were created based on (1) time until measurement of outcome, (2) type of test used to evaluate outcome, and (3) blinding. The difference

was then calculated between the proportion in the antibiotic group and those in the control group that experienced clearance of otitis media with effusion. The results of the meta-analyses, shown in Table 5, are the absolute differences between rate of clearance of otitis media with effusion with antibiotics and rate of clearance without. That is, if otitis media with effusion cleared in 22 percent of cases with antibiotics and in 19 percent without antibiotics, Table 5 shows a 3 percent difference, with a confidence interval for this difference that depends on the sizes of study populations included in the analysis. A negative difference indicates that the rate of clearance of otitis media with effusion was greater in the group of patients not receiving antibiotic therapy.

Panel subgroup evaluation of reports of antibiotic therapy studies originating at the University of Pittsburgh resulted in exclusion of the data from the two reports (Mandel, Rockette, Bluestone, et al., 1987; Cantekin, McGuire, and Griffith, 1991) for determining the effectiveness of antibiotics on otitis media with effusion, due to difficulties with the studies' methodologies. Data from the second report (Cantekin, McGuire, and Griffith, 1991) were ultimately used in meta-analysis 5 (Table 5) because of a lack of data from other sources, but were excluded from the final results reported in meta-analysis 8.

Results of note in Table 5 are the finding of a much greater difference between the antibiotic therapy and control groups when studies used only tympanometry as an outcome measure for otitis media with effusion compared to use of a combination of otoscopy and tympanometry. This difference is unexplained. In turn, the studies using hearing test results as the outcome measure for otitis media with effusion show a much greater difference between antibiotic and control groups than do studies using a combination of otoscopy and tympanometry. A number of factors can account for this difference: (1) not all young children with otitis media with effusion have a clinically significant hearing loss, (2) hearing evaluation results have a greater degree of inaccuracy in young children than in older children and adults, and (3) the meta-analysis was performed on only a few studies.

The above results showing some improvement, albeit small, in clearance of otitis media with effusion with antibiotic treatment do not answer questions about optimal use of this therapy. For example, what is the advantage to the patient of early clearance of otitis media with effusion? Without knowing this advantage, how can parents and health care providers balance this benefit against the potential adverse effects of antibiotic therapy? What is the overall cost-effectiveness of antibiotic therapy, given that no information is available about the degree to which this therapy can decrease the need for more expensive interventions (hearing evaluation and surgery) after 3 to 6 months of otitis media with effusion? One study (Podoshin, Fradis, Ben-David, et al., 1990) that examined outcomes at 2 months showed a 26.5 percent improvement in clearance of otitis media with effusion when antibiotics were used,

Table 5. Results of eight meta-analyses of the difference in resolution of otitis media with effusion treated by antibiotic agents and controls as a function of study design

Guideline meta-analysis number	Study types included in meta-analysis	Meta-analysis result[1]	95% Confidence interval
1	Blinded studies with outcomes measured at 10 to 14 days[2]	7.6%	-1% to 14%
2	Blinded studies with outcomes measured at 4 to 6 weeks[3]	18.5%	1.7% to 34.2%
3	All studies with outcomes measured at 10 to 14 days[4]	16.0%	3.7% to 28%
4	All studies with outcomes measured at 4 to 6 weeks[5]	23.4%	9.8% to 36.1%
5	Blinded studies using audiometric outcomes[6]	15.4%	-17.8% to 46.4%
6	Blinded studies using tympanometric outcomes[7]	30.8%	20.1% to 40.7%
7	Blinded studies using otoscopic/ tympanometric outcomes[8]	2.8%	-4.6% to 10.3%
8	All blinded studies[9]	14.0%	3.6% to 24.2%

[1] Absolute difference in proportion of children experiencing resolution of otitis media with effusion for group treated with antibiotic versus control group.
[2] Schwartz and Rodriguez, 1982; Daly, Giebink, Batalden, et al., 1991; Schloss, Dempsey, Rishikof, et al., 1988; Mandel, Rockette, Paradise, et al., 1991; Moller and Dingser, 1990.
[3] Schwartz and Rodriguez, 1982; Thomsen, Sederberg-Olsen, Balle, et al., 1989; Marks, Mills, and Shaheen, 1981; Mandel, Rockette, Paradise, et al., 1991; deCastro, Jaeger, Martin, et al., 1982; Varsano, Volovitz, and Mimouni, 1985.
[4] Schwartz and Rodriguez, 1982; Daly, Giebink, Batalden, et al., 1991; Ernstson and Anari, 1985; Giebink, Batalden, Le, et al., 1990; Schloss, Dempsey, Rishikof, et al., 1988; Mandel, Rockette, Paradise, et al., 1991; Moller and Dingser, 1990.
[5] Schwartz and Rodriguez, 1982; Thomsen, Sederberg-Olsen, Balle, et al., 1989; Marks, Mills, Shaheen, et al., 1981; Corwin, Weiner, and Daniels, 1986; Giebink, Batalden, Le, et al., 1990; Healy, 1984; Mandel, Rockette, Paradise, et al., 1991; deCastro, Jaeger, Martin, et al., 1982; Varsano, Volovitz, and Mimouni, 1985.
[6] Cantekin, McGuire, and Griffith, 1991; Podoshin, Fradis, Ben-David, et al., 1990; deCastro, Jaeger, Martin, et al., 1982.
[7] Thomsen, Sederberg-Olsen, Balle, et al., 1989; Podoshin, Fradis, Ben-David, et al., 1990; Marks, Mills, and Shaheen, 1981; deCastro, Jaeger, Martin, et al., 1982.
[8] Daly, Giebink, Batalden, et al., 1991; Schloss, Dempsey, Rishikof, et al., 1988; Mandel, Rockette, Paradise, et al., 1991; Moller and Dingser, 1990.
[9] Schwartz and Rodriguez, 1982; Thomsen, Sederberg-Olsen, Balle, et al., 1989; Marks, Mills, and Shaheen, 1981; Mandel, Rockette, Paradise, et al., 1991; Daly, Giebink, Batalden, et al., 1991; Schloss, Dempsey, Rishikof, et al., 1988; Moller and Dingser, 1990; Podoshin, Fradis, Ben-David, et al., 1990; deCastro, Jaeger, Martin, et al., 1982; Varsano, Volovitz, and Mimouni, 1985.

but longer term studies are needed to determine whether this effect is simply hastening clearance of effusion in children who would experience resolution without treatment, or promoting clearance in children who would not otherwise experience resolution of the effusion.

Adverse Effects of Antibiotics

Adverse effects of antibiotic therapy range from common to rare and from nuisance to life-threatening. The quality of published evidence linking antibiotic therapy to adverse effects is generally of poor quality, dominated by anecdotes and case reports, mostly in older children and adults. Nevertheless, potentially serious adverse effects—especially allergic reactions—do occur with this therapy in young children. The most common adverse effects of antibiotic drug therapy are gastrointestinal, with diarrhea occurring in about 9 percent of children treated with 20-40 mg/kg/day of amoxicillin with clavulanic acid (Table 6). Dermatologic reactions can occur in 3 to 5 percent of cases; severe anaphylactic reactions occur much less frequently; severe hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory adverse effects are more rare still (Table 6). Finally, there is concern that unnecessary use of antibiotics might lead to antimicrobial drug resistance and potentially more serious illness with later episodes of infection.

Steroid Therapy

Recommendation: Steroid medications are not recommended for treatment of otitis media with effusion in a child of any age. *[Based on limited scientific evidence and Panel majority opinion.]* **The Panel makes no statement regarding the use of steroid medications for conditions other than otitis media with effusion.**

The literature on use of adrenocorticosteroid medications to treat otitis media with effusion is growing rapidly. The Panel identified 10 controlled studies and one meta-analysis in which results of this therapy were analyzed. In most of these studies, steroid therapy for otitis media with effusion was of short duration (4 to 10 days), and systemic agents were used. The most frequently used steroid regimen was 1 mg/kg/day prednisone for 2 to 4 days followed by dosage tapering.

Efficacy of Steroid Agents

A single published meta-analysis of steroids alone or in combination with antibiotics found that both regimens were associated with increased likelihood of resolution of otitis media with effusion (Rosenfeld, Mandel, and Bluestone, 1991). Data on steroid therapy for otitis media with effusion share some characteristics with the data on antibiotic therapy for

Table 6. Adverse effects of antibiotic medications most often prescribed for otitis media in children

Antibiotic	Adverse reactions
Amoxicillin/ ampicillin	Diarrhea, usually mild and dose-related (20-30%). Cutaneous allergic reaction (3-5%). Rarely: hematologic, renal, hepatic effects.
Amoxicillin/ clavulanic acid	Diarrhea (9%). Nausea and vomiting (4%). Skin rashes/urticaria (3%). Rarely: hematologic, renal, hepatic effects (mostly in adults).
Cefaclor	Diarrhea (2.5%). Rarely: hematologic, central nervous system, renal, hepatic, dermatologic reactions; serum sickness (more common with cefaclor than with other antibiotics).
Cotrimoxazole	Skin rashes/urticaria (2%). Nausea, vomiting, diarrhea. Rarely: serious dermatologic reaction (less than 0.1%); hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, respiratory effects. Rare fatalities due to sulfonamides.
Erythromycin	Gastrointestinal effects (dose-related; 2-2.5% for ethylsuccinate or estolate salt administered to children). Subclinical elevations of liver function enzymes (5%). Rarely: serious adverse effects reported for most organ systems.
Sulfisoxazole	Gastrointestinal effects, uncommon (less than 1%). Rarely: serious hematologic (e.g., blood dyscrasias), dermatologic (e.g., Stevens-Johnson syndrome), neurologic, allergic reactions (less than 0.1%).

Source: Computerized Clinical Information System, 30 June 1993 ed. (MICROMEDEX, Inc., Denver, CO).

this condition. Studies report on the use of various steroid agents, and on use of steroids alone or steroid-antibiotic combination therapy with different antibiotic agents. Patient populations and study designs vary, and different techniques are used to measure outcomes.

The Panel performed several hierarchical Bayesian meta-analyses of the literature on steroid therapy for otitis media with effusion. Studies were not weighted for this analysis based on study design, as they had been in the previously published meta-analysis.

Steroid Therapy Compared to Placebo. Data from three reports of studies comparing steroid medications to placebo for treatment of otitis media with effusion were combined (Niederman, Walter-Buchholtz, and Jabalay, 1988; Macknin and Jones, 1985; Giebink, Batalden, Le, et al., 1990). Data were analyzed at two different times (2 weeks and 4 to

6 weeks) after treatment. The difference in mean improvement of otitis media with effusion 2 weeks after treatment was 18.4 percent (not statistically significant; the 95 percent confidence interval was [-3.4%, 38.6%]) in favor of steroid therapy. By 4 to 6 weeks after treatment the difference in mean improvement was 4.5 percent (not statistically significant; the 95 percent confidence interval was [-11.7%, 20.6%]). The mean differences in favor of steroid therapy indicate a trend for steroid therapy alone to promote improvement of otitis media with effusion. However, the small sample sizes in these studies, and the fact that confidence intervals for the meta-analysis include zero, indicate that this therapy provides no statistically significant benefit over placebo. In addition, the decreasing trend in improvement (from 18.4 percent to 4.5 percent) with time indicates that any benefits of steroid therapy alone are short-lived; any later improvements would be difficult to distinguish from improvements due to spontaneous resolution of otitis media with effusion.

Antibiotic-Steroid Therapy Compared to Antibiotics Alone. Five studies were examined for meta-analysis of antibiotic-steroid therapy compared to antibiotic therapy alone as treatment for otitis media with effusion. The time to measurement of results varied from 1 week to 2 months after treatment, and various antibiotic agents were used in the studies.

Analysis of four of these studies (Schwartz, Puglese, and Schwartz, 1980; Berman, Grose, Nuss, et al., 1990; Podoshin, Fradis, Ben-David, et al., 1990; Lambert, 1986), one of which (Podoshin, Fradis, Ben-David, et al., 1990) had not been available when the earlier (Rosenfeld, Mandel, and Bluestone, 1991) meta-analysis was performed, showed a difference in mean improvement for antibiotic-steroid therapy compared to antibiotic therapy alone of 25.1 percent (not statistically significant; the 95 percent confidence interval was [-1.3%, 49.9%]). The fifth study (Persico, Podoshin, and Fradis, 1987) was excluded from this Guideline meta-analysis because, although the study reported on a large sample of patients, the patients were not assigned randomly to study groups.

Results of the meta-analysis of existing studies closely approach but do not reach statistical significance, but they indicate a rather high probability that the antibiotic and steroid combination is more effective than antibiotic alone. Additional or larger studies will be needed to prove whether this difference exists.

Antibiotic-Steroid Therapy Compared to Placebo. Only three studies were found that examined the effects of antibiotic-steroid therapy compared to placebo (Berman, Grose, and Zerbe, 1987; Podoshin, Fradis, Ben-David, et al., 1990; Lildholdt and Kortholm, 1982), and in one of these studies beclamethasone nasal spray was used rather than a systemic steroid agent (Lildholdt and Kortholm, 1982). Meta-analysis of the results, measured in the studies between 1 and 2 months after treatment of otitis media with effusion, showed a mean difference in improvement of otitis

media with effusion due to antibiotic-steroid therapy of 21.4 percent (not statistically significant; the 95 percent confidence interval was [-1.4%, 42.6%]).

When the results of the three meta-analyses (efficacy of steroid versus placebo; antibiotic-steroid versus antibiotic, and antibiotic-steroid versus placebo) were compared, a paradox arose:

- Antibiotic-steroid combination therapy led to more improvement in otitis media with effusion than did antibiotic therapy alone when both were compared to placebo.
- However, steroid therapy alone led to less improvement in otitis media with effusion compared to placebo than did antibiotic-steroid therapy compared to antibiotic therapy alone.
- Furthermore, improvement with antibiotic-steroid therapy versus antibiotic alone was significantly better than improvement with antibiotic-steroid therapy versus placebo.
- Similarly, antibiotic alone resulted in less improvement than placebo in studies comparing antibiotic-steroid therapy to antibiotic alone or to placebo.

These results imply that antibiotic therapy slows the rate of resolution of otitis media with effusion—an implication that is not compatible with results of controlled studies of antibiotics versus placebo.

This paradox can be explained partially by differences among studies in times at which outcomes were measured. All but one of the studies of antibiotic-steroid therapy versus antibiotic therapy alone examined resolution of otitis media with effusion 3 weeks or less after treatment. Studies of antibiotic-steroid therapy versus placebo, however, all recorded outcomes 1 to 2 months after therapy. As with steroid therapy alone, when steroid is combined with an antibiotic agent, an early enhancement of outcome can result that is lost with time; by 1 to 2 months after treatment, small effects of steroid therapy can be difficult to distinguish from spontaneous resolution of otitis media with effusion. Variations in time to recorded outcome cannot totally explain differences in study results; there appear to have been considerable variations in patient populations for these studies, either according to site or selection. In summary, additional data are needed before a recommendation can be made for the utilization of steroids to treat otitis media with effusion.

Adverse Effects of Steroids

Steroid medications can have adverse effects, but, as with antibiotic medications, the quality of published evidence is poor, dominated by reports of cases, almost all older children and adults. The Panel identified agitation, behavior changes, sleeplessness, increase in appetite, and weight gain as possibly common in children who have undergone short-term steroid therapy. Serious or rare adverse effects of steroid therapy include

gastrointestinal disorders, angina, Cushing's disease, and (by anecdotal report) disseminated varicella in young children who had been exposed to varicella in the month before administration of steroid medication. The small sample sizes in controlled studies and the notable adverse effects of steroid medications led the Panel to recommend that use of steroid agents is still investigational for treatment of otitis media with effusion. If used to treat otitis media with effusion, steroid drugs should only be administered to children who have had varicella.

Antihistamine/Decongestant Therapy

Recommendation: Antihistamine and/or decongestant agents are not recommended for treatment of otitis media with effusion. *[Strong recommendation based on evidence that can be generalized to a child of any age.]* **The Panel makes no statement regarding the use of antihistamine and/or decongestant medications for conditions other than otitis media with effusion.**

Antihistamine and decongestant medications have been used separately or together for decades to treat otitis media with effusion. The Panel found, however, that the four randomized controlled studies of this therapy failed to show a statistically significant effect of these medications in resolving otitis media with effusion.

The first reported study of antihistamine/decongestant therapy for otitis media with effusion was a three-armed study of decongestant alone (phenylpropanolamine), decongestant with antihistamine (phenylpropanolamine with brompheniramine maleate), and placebo. The results showed weak negative trends for both active treatments against placebo, not reaching statistical significance (Haugeto, Schroeder, and Mair, 1981).

The second published report of antihistamine/decongestant therapy for otitis media with effusion was a double-blinded study of the combination chlorpheniramine maleate and pseudoephedrine hydrochloride in 553 children. The medication showed a very weak ($p=0.74$) negative tendency to resolve otitis media with effusion in children with unilateral effusion and a very weak ($p=0.67$) positive tendency to resolve effusion in those with bilateral effusion (Cantekin, Mandel, Bluestone, et al., 1983).

The third study in which antihistamine and decongestant agents were evaluated for otitis media with effusion was a double-blinded study in which antihistamine (chlorpheniramine) alone, decongestant (pseudoephedrine) alone, or placebo was administered. The decongestant showed a very weak positive trend and the antihistamine showed a very weak negative trend toward more effective resolution of otitis media with effusion compared to placebo or the other active agent. The results were not statistically significant, however (Dusdieker, Smith, Booth, et al., 1985).

The last trial the Panel examined in this category was a three-arm, double-blinded study of antibiotic (amoxicillin), antibiotic with antihistamine/decongestant (amoxicillin with chlorpheniramine maleate and pseudoephedrine hydrochloride), and placebo. In this study, addition of antihistamine/decongestant medications to antibiotic therapy showed a weak positive trend for improvement in otitis media with effusion, but the added effect of antihistamine/decongestant therapy was not statistically significant (Mandel, Rockette, Bluestone, et al., 1987).

Meta-analysis of the results reported in these four studies was performed for this Guideline by the hierarchical Bayes method. This meta-analysis showed that the antihistamine/decongestant combination had no effect on resolution of otitis media with effusion (mean, -0.009; 95 percent confidence interval [-0.036, 0.054]).

Antihistamine/decongestant medications can also have adverse effects, including insomnia, drowsiness, behavior changes, changes in blood pressure, and seizures.

7 Guideline: Surgical Therapies

Surgical intervention is often chosen for the treatment of persistent middle ear effusion. Bilateral myringotomy with insertion of tympanostomy tubes is the most frequently performed procedure. The Panel also examined adenoidectomy, with or without tonsillectomy.

Myringotomy with Tubes

Recommendation: Myringotomy with or without insertion of tympanostomy tubes should NOT be performed for initial management of otitis media with effusion in an otherwise healthy child. *[Strong recommendation based on evidence that otitis media with effusion resolves spontaneously in most cases and lack of conclusive evidence that a short period of otitis media with effusion has deleterious effects on otherwise healthy children.]*

Option: Antibiotic therapy OR bilateral myringotomy with insertion of tympanostomy tubes may be chosen to manage bilateral otitis media with effusion that has lasted a total of 3 months in an otherwise healthy child age 1 through 3 years who has a bilateral hearing deficit (defined as 20 decibels hearing threshold level or worse in the better-hearing ear). *[Based on limited scientific evidence and Panel consensus.]*

Recommendation: Bilateral myringotomy with insertion of tympanostomy tubes is recommended to manage bilateral otitis media with effusion that has lasted a total of 4 to 6 months in an otherwise healthy child age 1 through 3 years who has bilateral hearing deficit (defined as 20 decibels hearing threshold level or worse in the better-hearing ear). *[Moderate recommendation based on limited scientific evidence and strong Panel consensus.]*

Myringotomy with insertion of tympanostomy tubes is most often performed under general anesthesia in an ambulatory surgical center. Some physicians perform this procedure in an office setting with sedation and local anesthesia. Statistics from the National Hospital Discharge Survey for 1987 showed a 71 percent decline between 1977 and 1987 in the rate of myringotomy with or without tube insertions performed as an inpatient procedure, from 216,000 to 62,000 procedures (430 to 118 procedures per 100,000 population) (Derkay, 1993). Balancing this trend, however, is the increasing rate at which many procedures, including myringotomy with or without tube insertion, are performed in free-standing surgical centers. The reported rate for myringotomy with or without tubes performed in such a setting in 1986 was nearly 58,000 cases (Henderson, 1986).

Tympanostomy tubes are available in a myriad of designs, most constructed from plastic and/or metal. Variations in tube design reflect attempts to improve ease of tube insertion or removal and to prolong the period of tube retention in the tympanic membrane. Data comparing outcomes for tubes of various designs are sparse, however, and the Panel assumed that there were no notable differences between available tympanostomy tubes.

Benefits of Tympanostomy Tubes

The principal benefit of myringotomy with insertion of tympanostomy tubes is the restoration of hearing to pre-effusion threshold: removal of the middle ear effusion permits normal vibration of the tympanic membrane and middle ear bones, leading to more efficient transmission of sound across the middle ear to the inner ear. While patent and in place, tympanostomy tubes also permit ventilation of the middle ear tissues, allow for equalization of air pressure across the tympanic membrane, and can prevent further accumulation of fluid or mucus in the middle ear (van Cauwenberge, Cauwe, and Kluyskens, 1979).

There is abundant anecdotal evidence from parents that children are less irritable, sleep better, and communicate better after myringotomy with tympanostomy tube insertion. Parents also reportedly appreciate a return to normal listening levels of volume on the family television set after a child's hearing impairment has been reversed. There are, however, no controlled studies or even case series to document these effects.

Potential Harms of Tympanostomy Tubes

Morbidity associated with myringotomy and insertion of tympanostomy tubes can include external auditory canal wall laceration, persistent otorrhea, granuloma formation at the myringotomy site, cholesteatoma, and permanent tympanic membrane perforation (Kilby, Richards, and Hart, 1972; Skinner, Lesser, and Richards, 1988; Lildholdt, 1983; Gates, Avery, Prihoda, et al., 1986, 1988; Balkany, Arenberg, and Steenerson, 1986). Structural changes in the tympanic membrane, such as flaccidity, retraction, and/or tympanosclerosis, can also occur, especially in cases of repeated tube insertions (Maw, 1991; Lildholdt, 1983). As high a proportion as 30 percent of children can need to undergo repeat tympanostomy tube insertion within 5 years after the initial surgery (Maw, 1991).

The literature review allowed the Panel to assess the frequency of two specific complications of myringotomy with tympanostomy tube insertion—tympanosclerosis and postoperative otorrhea. Meta-analysis of data from two studies showed a risk of tympanosclerosis of 51 percent (95 percent confidence interval [43%, 58%]) (Lildholdt, 1983; Maw, 1991). The possible effects of tympanosclerosis on long-term hearing are

not known, but the Panel estimated from experience that they would be small. The risk of postoperative otorrhea was calculated by meta-analysis of data from three studies to be 13 percent (95 percent confidence interval [5.5%, 21%]) (Baldwin and Aland, 1990; Gates, Avery, Prihoda, et al., 1986, 1988).

Other disadvantages of tympanostomy tubes include the risks associated with the general anesthesia or substantial sedation required for the procedure (Markowitz-Spence, Brodsky, Syed, et al., 1990) and possible limitations on the child's activity while tubes are in place. Many physicians recommend the use of ear plugs to keep water from the ear canal during bathing or swimming because of evidence indicating a higher risk of infection and otorrhea related to water contamination (Arcand, Gauthier, Bilodeau, et al., 1984).

Another problem complicating tube placement is persistent eardrum perforation. Finally, intrusion of the tube into the middle ear cleft instead of normal extrusion into the external ear canal can occur. Because records are not kept of the fate of every tympanostomy tube, the incidence of this complication is not known. It could, however, result in increased risk of further episodes of otitis media, as well as tympanomastoiditis, cholesteatoma, or infection due to the foreign body.

Adenoidectomy

Recommendation: Adenoidectomy is not recommended for treatment of otitis media with effusion in a child age 1 through 3 years in the absence of specific adenoid pathology. *[Based on limited scientific evidence and strong Panel consensus.]*

Adenoidectomy has been advocated for the treatment of middle ear effusion as an isolated procedure or in combination with tonsillectomy, or with myringotomy and insertion of tympanostomy tubes. This procedure is most often chosen when nasal obstruction, nasal discharge, snoring, and mouth breathing are present. Maw (1983) noted that, historically, adenoidectomy has been recommended when the eustachian tubes are occluded by hypertrophic adenoidal tissue, compromising middle ear ventilation, or when the adenoids appear to be a focus of ascending eustachian tube infection. Absolute size of adenoid tissue, however, is not related to outcome of surgical management of otitis media with effusion, regardless of the type of surgical procedure (Gates, Avery, Cooper, et al., 1989).

Statistics from the National Hospital Discharge Survey show a decline in the frequency with which adenoidectomy is performed in children younger than age 15 years as an inpatient procedure, from 83,000 procedures in 1978 to 14,000 procedures in 1986 (Derkay, 1993). It is likely that the current frequency of adenoidectomy is somewhat higher than this, however, because of the trend for such procedures to be

performed increasingly in outpatient facilities of hospitals or in free-standing ambulatory surgical centers: in 1986, one-fifth of tonsillectomy procedures (with or without adenoidectomy) were performed in such outpatient settings. Concurrent with the change in setting for surgery, indications for adenotonsillectomy changed dramatically: in 1978 obstructive sleep apnea was not listed at all as an indication for this surgery, but in 1987 this diagnosis was the indication for adenotonsillar surgery in one-third of patients of all ages.

Benefits of Adenoidectomy

For patients whose adenoids obstruct the nasopharynx, adenoidectomy has the immediate benefit of relief of mouth breathing and snoring. Gates, Avery, Cooper, et al. (1989) reported a direct benefit to children 4 years or older both in reducing morbidity from otitis media with effusion and in reducing the number of recurrences. On the basis of these results, adenoidectomy is a clinical option for treatment of bilateral otitis media with effusion lasting 3 months or longer in a child age 4 years or older.

However, in studies of adenoidectomy that included children in the age range targeted for Guideline development, the results for children younger than 4 years could not be separated from results for older children (Maw and Herod, 1986), and the Panel found no literature reporting similar evidence of the efficacy of adenoidectomy in the primary management of otitis media with effusion in very young children. For this reason, the Panel does not recommend adenoidectomy as primary treatment for otitis media with effusion in children younger than 4 years. Although adenoidectomy is not recommended as a treatment for otitis media with effusion in children younger than 4 years, primary indicators for adenoidectomy may in some cases coexist with otitis media with effusion.

Potential Harms of Adenoidectomy

The morbidity associated with adenoidectomy for children of all ages includes the risks of general anesthesia. A report by the Baltimore Anesthesia Study Committee found that since the mid-1970s anesthesia-related mortality for children younger than 15 years has been less than 1 per 10,000 (Motoyama, 1990). An additional risk is significant postoperative bleeding. No reports of morbidity or mortality from adenoidectomy alone were found. However, a report of case-fatality rates in Ontario reported a death rate of 0.004 percent (2 deaths among 52,938) from combined tonsillectomy and adenoidectomy operations between 1968 and 1973 (Vayda, Lyons, and Anderson, 1977). Pratt (1970) reported an estimate of similar magnitude—0.006 percent—from mortality of 6,175,729 tonsillectomy and adenoidectomy procedures performed by 3,617 board-certified U.S. otolaryngologists; deaths were due in almost equal parts to anesthesia factors, cardiac arrest, and hemorrhage. A recent

review of 3,488 tonsil and adenoid procedures performed between March 1987 and April 1990 reported a hemorrhage rate of 0.49 percent (Yardley, 1992).

Candidates for adenoidectomy must be selected with care, because when the procedure is performed in a child with a submucous or occult submucous cleft of the palate, the risk is high that adenoidectomy can be followed by velopharyngeal insufficiency and other speech impairments.

The risk of postoperative bleeding, coupled with the lack of consistent evidence that adenoidectomy is effective in treating otitis media with effusion in this age group, led the Panel to decide that adenoidectomy is not an appropriate primary treatment for uncomplicated middle ear effusion in children younger than age 4 years.

Tonsillectomy

Recommendation: Tonsillectomy should not be performed, either alone or with adenoidectomy, for the treatment of otitis media with effusion in a child of any age. *[Strong recommendation based on limited scientific evidence and strong Panel consensus.]*

Evidence of the lack of efficacy of tonsillectomy for otitis media with effusion was inferred from a single randomized controlled study comparing adenotonsillectomy to adenoidectomy (Maw and Herod, 1986). Although tonsillectomy alone was not studied, the results from this study show that adding tonsillectomy to adenoidectomy (and, therefore, tonsillectomy alone) is not justified for the treatment of otitis media with effusion. Furthermore, for the older children in this study, adenotonsillectomy offered no significant advantage over simple adenoidectomy for the treatment of otitis media with effusion. The authors noted that the added morbidity of tonsillectomy with adenoidectomy does not at present justify recommendation for removal of the tonsils in addition to adenoidectomy in children with otitis media with effusion; rather, tonsillectomy in these children should be performed for tonsillar pathology per se and not with regard to the status of the middle ear.

8 Guideline: Allergy

No Recommendation: No recommendation is made regarding allergy management as a treatment for otitis media with effusion. *[Based on insufficient evidence clarifying the relationship between allergy and otitis media with effusion.]*

The close anatomic relationships between the nasopharynx, eustachian tube, and middle ear have led many experts to examine the role that allergy might play in the occurrence of eustachian tube malfunction and chronic otitis media with effusion. Hall and Lukat (1981) reviewed studies of the association between otitis media with effusion and allergy, and found that three articles estimated an allergic origin of otitis media with effusion in 20 to 90 percent of cases (Hardy, 1961; Shambaugh, 1975; Mueller, 1970). However, they found that in a number of other studies allergy was shown to be of little importance in the etiology of otitis media with effusion (Robinson and Nicholas, 1951; Kapur, 1964; Schuknecht, 1964; Senturia, Jessert, Carr, et al., 1958; Suehs, 1952).

The Panel examined 22 articles in its initial review of allergy and otitis media, but the majority of these studies did not meet the Panel's criteria for inclusion in the evidence. After exclusion of case reports and studies that included adult subjects, seven articles remained, and these were descriptive rather than reports of randomized controlled studies. Because methods used in these studies to measure the association of allergy and otitis media were not commensurable, the data could not be combined for meta-analysis.

Atopy as a Risk Factor

The Panel found six studies that examined atopy as a risk factor for otitis media with effusion. Because the results of these studies were conflicting and some patients were older than the Guideline target patient, no conclusion could be drawn from the data as a group.

No association between atopy and otitis media with effusion was found in a study reported by Black (1985).

In a Japanese study (Tomonaga, Kurono, and Mogi, 1988), researchers determined that allergic rhinitis was present in 50 percent of 259 patients (mean age 6 years) in whom otitis media with effusion had been diagnosed, and otitis media with effusion was present in 21 percent of 605 patients (mean age 9 years) in whom allergic rhinitis had been diagnosed. Among 108 children (ages 5 to 8 years, mean 6 years) in whom neither condition had been diagnosed, the incidences of allergic rhinitis, otitis media with effusion, and both of these conditions were 17 percent, 6 percent, and 2 percent, respectively.

Another study (Kraemer, Richardson, Weiss, et al., 1983) compared risk factors for persistent middle ear effusion among 76 children admitted for insertion of tympanostomy tubes and 76 controls matched by age, sex, and season of admission for a general surgical procedure. Results of this study showed a nearly fourfold increase in the risk of persistent middle ear effusion in children who had atopic symptoms for more than 15 days per month, although this statistic was uncorrected for a large number (more than 15) of other possible risk factors for otitis media with effusion. When the single risk factor of atopic symptoms for more than 1 day per month was examined, the relative risk for otitis media with effusion was only 0.5.

Bernstein, Lee, Conboy, et al. (1983) reported on a prospective study of the role of hypersensitivity mediated by immunoglobulin E in the occurrence of otitis media with effusion. Subjects for this study were 77 children age 2 to 18 years with recurrent otitis media with effusion who had undergone at least two myringotomies with insertion of tympanostomy tubes. The finding that 32 (42 percent) of the subjects had allergic rhinitis mediated by immunoglobulin E suggests that in patients with allergic rhinitis, otitis media with effusion can result from hypersensitivity mediated by immunoglobulin E. However, the middle ear might be the target organ in only 15 to 20 percent of patients with otitis media with effusion and allergic rhinitis. In this study, the middle ear was the target organ in only 5 (7 percent) of the 77 patients with recurrent otitis media with effusion. This finding, and the fact that more than half (58 percent) of children with recurrent otitis media with effusion in this study did not have allergic rhinitis and were clearly nonallergic, led the authors to conclude that the role of atopy in otitis media with effusion is still unresolved.

In another study, levels of immunoglobulin E were measured in middle ear effusions and serum samples from 58 children age 6 months to 11 years (Boedts, de Groote, and van Vuchelen, 1984). Eight (14 percent) of the 58 patients had markedly elevated serum levels of immunoglobulin E, indicating that an atopic disorder was very likely. Although the authors note that their results and those of other studies do not support allergy as a major factor in the etiology of otitis media with effusion, the results do not rule out the possibility that otitis media with effusion might occur as a complication of allergic rhinitis.

Finally, Bernstein and Reisman (1974) studied allergy in a group of 200 children who had undergone one or more myringotomies with insertion of tympanostomy tubes. They found that 24 percent (46) of the 200 had allergy but that the incidence of allergy was 35 percent among children (n=88) who had undergone more than one myringotomy with insertion of tubes. The authors concluded that the middle ear is not an allergic organ, but that middle ear disease can be secondary to allergy elsewhere in the nasopharynx. However, six patients with recurrent otitis media with effusion and known allergies did not improve with several years of aggressive allergy treatment.

Hyposensitization as a Treatment

Two of the seven articles on allergy reported on the role of hyposensitization in otitis media with effusion (Hurst, 1990; Tomonaga, Kurono, and Mogi, 1988). Both studies were of case-control design, so that the researchers neither randomized subjects nor "blinded" clinicians as to whether patients were receiving hyposensitization treatment.

In the study reported by Hurst (1990), 20 patients between age 3 and 11 years who had a history of otitis media with effusion were offered hyposensitization; those who refused (3 patients) served as controls. In this study, 65 percent of the patients who chose (and complied with) allergy treatment remained disease-free for more than 3 years. During episodes of noncompliance with the allergy treatment, otitis media with effusion returned.

In the Japanese study (Tomonaga, Kurono, and Mogi, 1988), 12 of 41 children with allergic rhinitis who had also had tympanostomy tubes inserted to manage associated otitis media with effusion underwent hyposensitization therapy. In these children, the mean time from extrusion of the tympanostomy tube to recurrence of otitis media with effusion was more than 11 months, compared to a mean time to recurrence in the untreated 29 children of less than 3 months.

Because patients in these studies were older than the target patient for the Guideline, and because the study designs and numbers of patients studied were inadequate, the Panel could not estimate the effectiveness of hyposensitization therapy for otitis media with effusion in children age 1 through 3 years. Furthermore, anaphylactic reactions to hyposensitization have been reported in as many as 6 percent to 11 percent of patients (Ostergaard, Kaad, and Kristensen, 1986; Mosbech, Dirksen, Dreborg, et al., 1990). For some patients, this significant risk of anaphylaxis might well outweigh the possible benefits of hyposensitization for the treatment of otitis media with effusion.

Although the seven reports on the topic of allergy and otitis media with effusion propose plausible theories concerning a connection between allergic rhinitis, eustachian tube physiology, and the development of otitis media, the data available do not fully support or elucidate the nature of the connection. Thus, the Panel could not make any statement regarding the impact of allergy or its treatment on the incidence or prevalence of otitis media with effusion in children.

9 Guideline: Other Therapies

No Recommendation: No recommendation is made regarding other therapies (chiropractic, holistic, naturopathic, traditional or indigenous, homeopathic) for the treatment of otitis media with effusion in the otherwise healthy child age 1 through 3 years.
[Based on lack of scientific evidence.]

Other therapies for the treatment of otitis media with effusion include chiropractic, holistic, naturopathic, traditional or indigenous, and homeopathic methods. The frequency with which these therapies are used in the United States and their cost are not known.

The Panel was unable to find any reports of randomized controlled studies of other therapies for otitis media with effusion in young children. Attempts to locate such data included a computer search of the literature, letters to schools of education in the relevant fields, and personal communication with practitioners of other treatment methods. In addition, representatives from societies and institutes of higher education for practitioners of these methods were invited to participate in the Open Meeting and to submit written testimony on this topic.

Because none of the submitted materials reported on data obtained in controlled studies, the Panel did not make any recommendation regarding other therapies for the treatment of otitis media with effusion in children. The Panel did find, however, that some of the other therapies are apparently without notable risk of morbidity and are inexpensive. Thus, the Panel recommended that randomized controlled studies of these therapies for otitis media with effusion in children be undertaken.

10 Cost Impact

The Panel commissioned an analysis of the cost of treating otitis media with effusion in young children. The contractor (Lewin-VHI, Inc.) was asked to determine current costs of treating otitis media with effusion and the potential impact on those costs of the Panel's recommendations for management. The full report will be available as an appendix to the *Guideline Technical Report.*

The cost analysis was complicated by several factors:

- Direct cost data were not available. The contractor used charges recorded in a health care claims data base compiled from more than 100 insurance companies by MEDSTAT Systems, Inc. Claims for all patients with specific ICD-9-CM diagnosis codes were extracted, thus removing claims for patients over age 17, those with nonrelevant medical care (i.e., intercurrent visit for another problem), and those with incomplete records, leaving a final working file of 129,081 outpatient claims and 579 inpatient claims covering 18,357 patients.
- Otitis media with effusion is a disease of children that can extend over many months, making it difficult to obtain complete information about a full episode of illness.
- Otitis media with effusion and recurrent acute otitis media overlap in claims data because of the use of nonspecific codes for otitis. Thus, although care was taken to use only selected codes (ICD-9-CM diagnostic codes 381.1 through 391.4) to retrieve data for Guideline cost analysis, researchers could not control for possible miscoding by health care providers or their staff. In addition, the codes used are for "chronic otitis," and these codes could mask a number of middle ear and upper airway conditions. Furthermore, the costs of treating otitis media with effusion are difficult to identify when charges are made at the same visit for other health care (e.g., concurrent medical care or well-child care).
- Costs of pharmacotherapy were not often included in the insurance claims data base because they are not usually covered by insurance. Thus, costs of pharmacotherapy were estimated by consulting standard published drug pricing information (the 1991 Drug Red Book) and adding the median Medicaid dispensing fee.
- Indirect cost estimates were limited to time and wages lost by parents, using 1991 Median Daily Earnings from the Bureau of Labor Statistics.
- Estimates include use of a therapy, initially considered an option by the Panel, that later in Guideline development was not recommended.

The results of the analysis show that 42 percent of children in the sample studied underwent myringotomy with tube placement and 6 percent underwent adenoidectomy; the remainder were treated nonsurgically.

Patients treated without surgery averaged 4.6 office visits, whereas those who underwent myringotomy with tube insertion averaged 5.5 office visits and those who underwent adenoidectomy averaged nearly 7 office visits for preoperative and postoperative treatment of an episode of otitis media with effusion.

Hearing testing was performed for 25.4 percent, 39.6 percent, and 44.6 percent of the children treated medically only, by myringotomy with tube insertion (before surgery), or by adenoidectomy (before surgery).

Extrapolating from data obtained for the cost analysis, it was estimated that 821,700 cases of otitis media with effusion occurred in 2-year-old children in 1991 and that $1.09 billion was actually spent for direct and indirect costs of care in these cases. The average cost per case across all treatment categories was $1,330. The average total costs per patient were $406, $2,174, and $3,433, respectively, for those treated medically, with myringotomy and insertion of tympanostomy tubes, and with adenoidectomy.

Predicting what might happen if the algorithm proposed in this Guideline entirely replaced current practice is hazardous because of the sensitivity of the result to many assumptions made during the process of cost analysis and to inherent limitations of claims-based data. For example, some of the parameters (e.g., an estimate that 30 percent of office visits coded as otitis media were for otitis media with effusion) were simply estimated by the Panel because data were unavailable. Despite the lack of adequate data, costs were calculated for care of otitis media with effusion in 2-year-old U.S. children in 1991 using strict adherence to the Guideline. The savings predicted were considerable (Table 7).

Table 7. Estimated 1991 costs of treating otitis media with effusion if Guideline recommendations had been implemented (United States, 2-year-old children)

Cost component	1991 dollar amount[1]	Percentage of total cost[1]
Total cost	$246.6 million	100.0
Total cost incurred in first 3 months	$118.8 million	48.2
Cost of surgical treatment	$80.3 million	32.6
Indirect costs	$77.1 million	31.3
Pharmaceutical costs	$16.8 million	6.8

[1] Because most of the components overlap, the sums of the last four rows are greater than the total cost given in the first row.

Source: Lewin-VHI, Inc.

The Panel found no literature that examined the costs of treating otitis media with effusion in such a way that the results could be applied directly

to Guideline recommendations. After completing the rigorous evidence-based review conducted to arrive at recommendations for clinical interventions for otitis media with effusion, the Panel was skeptical about depending upon a single cost analysis for estimating how implementing these recommendations would affect costs of care. Some Panelists thought the Guideline recommendations closely approximated current practice; thus, the prediction that application of the Guideline might result in significant cost savings raised concerns about the methods used for cost analysis. In particular, the estimate from the claims data that 42 percent of children with otitis media with effusion underwent myringotomy with insertion of tympanostomy tubes was met with skepticism by some of the Panel members, because it is much higher than the percentage they have observed in clinical practice. Other Panel members viewed the Guideline recommendations as more conservative than current practice with respect to surgery and were not surprised by the prediction that application of the recommendations might lead to fewer surgical interventions and lower costs. In the aggregate, the Panel views the contractor's cost estimates as representing the extreme of what might occur if the Guideline recommendations were implemented. Individual Panel members' estimates of the effect of Guideline implementation on costs of care for otitis media with effusion ranged from no effect to significant savings in direct and indirect costs of managing this condition.

11 Research Issues

Members of the Panel were disappointed to find the medical literature voluminous but unenlightening on many important issues related to otitis media with effusion. General areas in which research studies are needed include natural history, diagnosis, prevention, interventions for, and long term outcomes of otitis media with effusion. The Panel hopes that well-designed randomized controlled studies will be conducted to answer the many important questions raised in its evidence-based review of the literature for development of this Guideline.

Natural History

It is characteristic of health care providers in the United States to intervene for otitis media with effusion, but the Panel was impressed by data suggesting that otitis media with effusion usually follows a benign course without treatment. Thus, although such a study might be difficult to implement because it runs counter to prevailing attitudes, research to document the natural course of otitis media with effusion is essential to the identification of factors that separate children at risk for serious consequences of this condition—and who therefore require treatment—from those who will do well if otitis media with effusion is not treated.

A key issue in research into the natural history of otitis media with effusion is the putative association of this condition with long-term adverse effects on speech and language development, learning, and behavior. There is general agreement that not treating a significant and/or long-lasting hearing impairment associated with otitis media with effusion could cause serious disability. However, little is known about the effects that fluctuating hearing loss can have on the long-term outcomes for otherwise normal children. Studies must be conducted to identify the combinations of patient characteristics and hearing loss that indicate risk of long-term problems. Factors that must be studied include:

- Child's age at onset of the hearing impairment.
- Duration of the hearing impairment.
- Severity of the hearing impairment.
- Child's social environment.
- Effect of fluctuation of hearing.

High-quality descriptive research studies are essential to definition of the proximal and long-term effects of hearing loss on speech, language, learning, and behavioral outcomes. Some of the linkages in the causal chain can be examined in children with hearing loss from causes other than otitis media with effusion.

Diagnosis

No data have been reported on the use of otoscopy and pneumatic otoscopy in typical practice settings, although these two tests are the foundation upon which diagnostic and treatment decisions are made by many, if not most, clinicians. Similarly, tympanometry is used by many clinicians, alone or in combination with otoscopy, to evaluate for otitis media, and yet the methods for and results of performing tympanometry in typical practice settings, especially in primary care, have not been documented. The Panel recommends that:

- Diagnostic criteria be clarified for use of otoscopy, pneumatic otoscopy, and tympanometry in typical practice settings, particularly primary care.
- A diagnostic algorithm combining tympanometry and pneumatic otoscopy—similar to that used in research—be developed for use in clinical practice settings.
- The correlation of hearing evaluation results with otitis media with effusion be examined in large study populations representative of those cared for in a typical clinical practice.

Control of Environmental Risk Factors

Available research suggests that environmental factors are associated with otitis media with effusion, but the data are descriptive and study results are open to criticism because of the research methods employed. Studies of impeccable design are needed on the associations between factors such as infant feeding practices, cigarette smoke, allergens, and child-care situations and the incidence, duration, complications, and other characteristics of otitis media and otitis media with effusion. Once associations have been identified, intervention studies should be conducted to determine the nature of the linkage(s) and whether controlling for the environmental factor(s) results in improved outcome for children with otitis media with effusion.

Intervention

Clinical studies must be conducted to determine whether treatment of any kind improves the outcome of otitis media with effusion in children. The studies must be designed:

- To involve enough children for the results to be statistically commanding.
- To involve patient populations similar to those seen in typical practice.
- To control adequately for multiple confounding variables so that the results are clinically meaningful.

The best studies to meet these needs would be multicenter. In addition, they must be long-term, because the most important clinical outcomes of

otitis media with effusion in children (speech, language, learning, behavior) may not be known until years after the intervention. For this reason, any recommendations, such as those made by the Panel in this Guideline, must be considered provisional until the results of such high-quality, long-term research confirm or refute their value.

Antibiotic Therapy

Although the Panel found a large body of literature on antibiotic therapy for otitis media with effusion, major deficiencies in study designs precluded consideration of much of the data. A second problem with reports of antibiotic drug studies is the tendency for investigators and scientific journal editors to publish only reports of studies in which a positive effect of the therapy is demonstrated. Thus, the Panel viewed somewhat skeptically even the small number of reports of well-designed antibiotic therapy studies that met criteria for inclusion in the evidence for Guideline development.

The Panel believes that clinical studies are urgently needed to examine the issues related to antibiotic therapy for otitis media with effusion. Such studies should:

- Involve large study populations.
- Involve study populations representative of typical clinical practice.
- Be placebo controlled.
- Measure clinically important outcomes.
- Measure patient compliance with the drug regimen.
- Document antibiotic resistance.
- Document adverse events.
- Establish sequence and duration of therapy with various antibiotic agents.

Steroid Therapy

The Panel found provocative but unconvincing recently reported data on the effectiveness of steroid medications alone and in combination with antibiotic agents to treat otitis media with effusion. Studies are needed in this area, and should:

- Involve large study populations.
- Involve study populations representative of typical clinical practice.
- Measure clinically important outcomes.
- Focus on a small number of antibiotic-steroid combinations.
- Identify the drug treatments that provide the best balance of high efficacy, low cost, and minimal number and severity of adverse effects.

Surgery

The long-term effects of surgery on speech, language, learning, and behavior have not been identified. In addition, little is known about the short-term benefits of surgery other than relief from middle ear effusion. Future research should include the development of methods to measure the child's and parent's experiences of the operation. In particular, studies are needed to quantify the observations of parents, reported so often anecdotally by practitioners, that the child improves in sleep, behavior, communication, and other ways after surgery. Future research is also needed to determine whether the effects of adenoidectomy in reducing morbidity and number of recurrences in otitis media with effusion can be generalized to younger children in the 1 to 3 year age range.

Allergy

The proposed linkage between allergy and otitis media with effusion is biologically plausible and, if validated, might open up important new avenues for intervention. High-quality descriptive studies should be followed by randomized controlled studies of therapy, focusing on clinically important outcomes as suggested for drugs and surgery.

Other Therapies

The Panel found the process of the Open Meeting, during which many individuals provided interesting testimony on other therapies, both enlightening and disappointing. The Panel was impressed by the variety and apparent safety of many of the proposed therapies, but was disappointed that none had been submitted to scientific study. The Panel suggests that research begin with those other therapies commonly provided that appear the least likely to have adverse effects. Study designs should be similar to those proposed for evaluation of drugs and surgery.

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Glossary

Acoustic reflectometry. A test using sound to evaluate the status of the middle ear.

Acute otitis media. Inflammation of the middle ear with signs or symptoms of middle ear infection.

Adenoidectomy. A surgical procedure to remove the adenoids (lymphoid tissue in the nasopharynx).

Antibiotic agent, drug, medication. A pharmaceutical preparation that kills bacteria causing infection. Antibiotic agents that have been used and studied for otitis media with effusion in children are believed to be effective for a broad spectrum of bacteria and are administered by mouth.

Conductive hearing loss. Decreased hearing acuity resulting from impaired transmission of sound between the eardrum and oval window (tissue dividing the middle and inner ears).

Decibel (db). A measure of the intensity of sound.

Environmental risk factors (for otitis media with effusion). Any of a number of factors in the child's physical, nutritional, or social surroundings that can be associated with otitis media with effusion. Factors discussed in the Guideline include infant feeding practices, passive smoking (smoke particles present in the air the child breathes as a result of another's active smoking of tobacco), and group child-care facility attendance.

Eustachian tube. A short tube that connects the middle ear space and the nasopharynx. The eustachian tube is normally closed; it usually opens with swallowing, yawning, or change in air pressure between the middle ear space and the nasopharynx.

Hearing evaluation. Testing conducted to estimate the patient's hearing sensitivity, auditory system integrity, and auditory function. Various tests are used, depending on the age of the patient and the need to define the characteristics of any hearing loss.

Hearing threshold level. The decibel value of the lowest-intensity sound detectable by the individual. When possible, hearing threshold level is measured in each ear separately. Hearing threshold level can be worsened in an ear with otitis media with effusion.

Middle ear. The part of the ear that includes the eardrum, auditory ossicles, facial nerve, and eustachian tube. The eustachian tube connects the middle ear to the nasopharynx.

Middle ear effusion. Fluid in the middle ear.

Myringotomy. An operation in which a small incision is made through the tympanic membrane (eardrum).

Myringotomy with insertion of tympanostomy tube(s). After myringotomy and suctioning of fluid from the middle ear, a small tube (tympanostomy tube) is inserted into the eardrum. This term is usually plural (myringotomy with insertion of tympanostomy tubes) because the procedure is most often performed on both ears. This procedure is most often performed to treat otitis media with effusion in children in order to remove the effusion, provide ventilation, and restore hearing.

Nasopharynx. Air passage connecting the nose and the throat. The eustachian tube opens into the nasopharynx.

Observation. Monitoring a child who has otitis media with effusion for signs and symptoms of effects on hearing or behavior or the occurrence of other middle ear disease.

Otitis media. Inflammation of the middle ear, with or without signs of fluid or infection.

Otitis media with effusion. Fluid in the middle ear without signs or symptoms of ear infection.

Otoscopy. Use of an instrument called an otoscope (a device that contains a light source and lenses attached to a speculum) to look directly at the tympanic membrane.

Persistent acute otitis media. Middle ear inflammation with signs of infection that does not resolve after initial treatment.

Pneumatic otoscopy. Use of an instrument called a pneumatic otoscope to both look at the tympanic membrane and observe its movement. A pneumatic otoscope is similar to an otoscope, with the added features of a means to seal the speculum in the ear canal and to create a slight increase in pressure and then a decrease in pressure in the ear canal. The changes in pressure allow the examiner to evaluate the mobility of the tympanic membrane.

Recurrent acute otitis media. Middle ear inflammation with signs of infection that occurs shortly after resolution of an episode of acute otitis media.

Steroid agent, drug, medication. A pharmaceutical preparation of adrenocorticosteroid hormone. The steroid medications that have been used to treat otitis media with effusion in children have been given by mouth or sprayed into the nose; duration of therapy has been a maximum of 7 to 10 days.

Tonsillectomy. A surgical procedure to remove the tonsils (a type of lymphoid tissue located in the throat).

Tympanic membrane. Also called the eardrum. A very thin disc of skin-like tissue about 1 centimeter in diameter that separates the outer ear (the ear canal) from the middle ear.

Tympanometry. A test of tympanic membrane compliance and middle ear pressure.

Tympanostomy tube. A tiny tube, usually of metal or plastic and about 0.5 centimeter long, that can be inserted after myringotomy to ventilate the middle ear.

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Numerous individuals and groups contributed time, effort, and expertise to the development of the Otitis Media Clinical Practice Guideline. Without the support of Panel members and consultants and those who provided peer review or pilot review of draft guidelines, and their collaboration toward a common goal, this Guideline would never have become a reality.

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Availability of Guidelines

For each clinical practice guideline developed under the sponsorship of the Agency for Health Care Policy and Research (AHCPR), several versions are produced to meet different needs.

The *Guideline Report* contains the *Clinical Practice Guideline*, with complete supporting materials including background information, methodology, literature review, scientific evidence tables, and a comprehensive bibliography.

The *Clinical Practice Guideline* and the *Quick Reference Guide for Clinicians* are companion documents for use as desk-top references for clinical decisionmaking in the day-to-day care of patients. Recommendations, algorithms or flow charts, tables and figures, and pertinent references are included.

The *Parent Guide*, available in English and Spanish, is an information booklet for the general public to increase consumer knowledge and involvement in health care decisionmaking.

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To order guideline products or to obtain further information on their availability, call the AHCPR Publications Clearinghouse at (800) 358-9295, or write to: P.O. Box 8547, Silver Spring, MD 20907.

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Quick Reference Guide for Clinicians
Number 12

Managing Otitis Media with Effusion in Young Children

- Diagnosis and Hearing Evaluation
- Environmental Risk Factors
- Therapeutic Intervention
- Algorithm

Otitis Media with Effusion
PS 022906

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

21

Attention Clinicians:

The *Quick Reference Guide for Clinicians, Managing Otitis Media with Effusion in Young Children*, was developed by the American Academy of Pediatrics under contract with the Agency for Health Care Policy and Research (AHCPR) and in consortium with the American Academy of Family Physicians and the American Academy of Otolaryngology–Head and Neck Surgery (the "Consortium"). With AHCPR approval, the Consortium convened an interdisciplinary, non-Federal panel comprising health care professionals and a consumer representative. Panel members were:

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For a description of the guideline development process and information about the sponsoring agency (AHCPR), see the *Clinical Practice Guideline, Otitis Media with Effusion in Young Children* (AHCPR Publication No. 94–0622). To receive copies of the *Clinical Practice Guideline*, as well as this *Quick Reference Guide for Clinicians, Managing Otitis Media with Effusion in Young Children* (AHCPR Publication No. 94–0623) and *Middle Ear Fluid in Children: Parent Guide* (AHCPR Publication No. 94–0624), call toll free 800-358-9295 or write the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907.

AHCPR invites comments and suggestions from users for consideration in development and updating of future guidelines. Please send written comments to Director, Office of the Forum for Quality and Effectiveness in Health Care, AHCPR, Willco Building, Suite 310, 6000 Executive Boulevard, Rockville, MD 20852.

Note: This *Quick Reference Guide for Clinicians* presents summary points from the *Clinical Practice Guideline*. The *Clinical Practice Guideline* provides more detailed analysis and discussion of the available research, health care decisionmaking, critical evaluation of the assumptions and knowledge of the field, considerations for patients with special needs, and references. Decisions to adopt any particular recommendation from any publication must be made by practitioners in light of available resources and circumstances presented by individual patients.

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Managing Otitis Media with Effusion in Young Children

Purpose and Scope

Otitis media (inflammation of the middle ear) is the most frequent primary diagnosis at visits to U.S. physician offices by children younger than 15 years. Otitis media particularly affects infants and preschoolers: almost all children experience one or more episodes of otitis media before age 6.

The American Academy of Pediatrics, the American Academy of Family Physicians, and the American Academy of Otolaryngology–Head and Neck Surgery, with the review and approval of the Agency for Health Care Policy and Research of the U.S. Department of Health and Human Services, convened a panel of experts to develop a guideline on otitis media for providers and consumers of health care for young children. Providers include primary care and specialist physicians, professional nurses and nurse practitioners, physician assistants, audiologists, speech-language pathologists, and child development specialists. Because the term otitis media encompasses a range of diseases, from acute to chronic and with or without symptoms, the Otitis Media Guideline Panel narrowed the topic. Two types of otitis media often encountered by clinicians were considered:

- **Acute otitis media**—fluid in the middle ear accompanied by signs or symptoms of ear infection (bulging eardrum usually accompanied by pain; or perforated eardrum, often with drainage of purulent material).
- **Otitis media with effusion**—fluid in the middle ear without signs or symptoms of ear infection.

The *Clinical Practice Guideline, Otitis Media with Effusion in Young Children*, and this *Quick Reference Guide for Clinicians, Managing Otitis Media with Effusion in Young Children*, based on the *Guideline*, discuss only otitis media with effusion. Further, the *Guideline* and this *Quick Reference Guide* narrow their discussion of the identification and management of otitis media with effusion to a very specific "target patient":

- A child age 1 through 3 years.
- With no craniofacial or neurologic abnormalities or sensory deficits.
- Who is healthy except for otitis media with effusion.

When the scientific evidence for management permitted, Guideline recommendations were broadened to include older children.

Highlights of Patient Management

Congenital or early onset hearing impairment is widely accepted as a risk factor for impaired speech and language development. In general, the earlier the hearing problem begins and the more severe it is, the worse its effects on speech and language development. Because otitis media with effusion is often associated with a mild to moderate hearing loss, most clinicians have been eager to treat the condition to restore hearing to normal and thus prevent any long-term problems.

Studies of the effects of otitis media with effusion on hearing have varied in design and have examined several aspects of hearing and communication skills. Because of these differences, the results cannot be combined to provide a clear picture of the relationship between otitis media with effusion and hearing. Also, it is uncertain whether changes in hearing due to middle ear fluid have any long-term effects on development. Evidence of dysfunctions mediated by otitis media with effusion that have persisted into later childhood, despite resolution of the middle ear fluid and a return to normal hearing, would provide a compelling argument for early, decisive intervention. There is, however, no consistent, reliable evidence that otitis media with effusion has such long-term effects on language or learning.

The following recommendations for managing otitis media with effusion are tempered by the failure to find rigorous, methodologically sound research to support the theory that untreated otitis media with effusion results in speech/language delays or deficits.

Recommendations and options were developed for the diagnosis and management of otitis media with effusion in otherwise healthy young children. The following steps parallel the management algorithm provided at the end of this booklet.

Diagnosis and Hearing Evaluation

1. Suspect otitis media with effusion in young children.

Most children have at least one episode of otitis media with effusion before entering school. Otitis media with effusion may be identified following an acute episode of otitis media, or it may be an incidental finding. Symptoms may include discomfort or behavior changes.

2. Use pneumatic otoscopy to assess middle ear status.

Pneumatic otoscopy is recommended for assessment of the middle ear because it combines visualization of the tympanic membrane (otoscopy) with a test of membrane mobility (pneumatic otoscopy). When pneumatic otoscopy is performed by an experienced examiner, the accuracy for diagnosis of otitis media with

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effusion may be between 70 and 79 percent.

3. Tympanometry may be performed to confirm suspected otitis media with effusion.

Tympanometry provides an indirect measure of tympanic membrane compliance and an estimate of middle ear air pressure. The positive predictive value of an abnormal (type B, flat) tympanogram is between 49 and 99 percent; that is, as few as half of ears with abnormal tympanograms may have otitis media with effusion. The negative predictive value of this test is better—the majority of middle ears with normal tympanograms will in fact be normal. Because the strengths of tympanometry (it provides a quantitative measure of tympanic membrane mobility) and pneumatic otoscopy (many abnormalities of the eardrum and ear canal that can skew the results of tympanometry are visualized) offset the weaknesses of each, using the two tests together improves the accuracy of diagnosis.

- **Acoustic reflectometry** has not been studied well enough for a recommendation to be made for or against its use to diagnose otitis media with effusion.
- **Tuning fork tests:** No recommendation is made regarding the use of tuning fork tests to screen for or diagnose otitis media with effusion, except to note that they are inappropriate in the youngest children.

4. A child who has had fluid in both middle ears for a total of 3 months should undergo hearing evaluation. Before 3 months of effusion, hearing evaluation is an option.

A change in hearing threshold is both a clinical outcome and a possible indicator of the presence of otitis media with effusion. Methods used to determine a child's hearing acuity will vary depending on the resources available and the child's willingness and ability to participate in testing. Optimally, air- and bone-conduction thresholds can be established for 500, 1,000, 2,000, and 4,000 Hz, and an air-conduction pure tone average can be calculated. This result should be verified by obtaining a measure of speech sensitivity. Determinations of speech reception threshold or speech awareness threshold alone may be used if the child cannot cooperate for pure tone testing. If none of the test techniques is available or tolerated by the child, the examiner should use his/her best judgment as to adequacy of hearing. In these cases, the health care provider should be aware of whether the child is achieving the appropriate developmental milestones for verbal communication.

Although hearing evaluation may be difficult to perform in young children, evaluation is recommended after otitis media with effusion has been present bilaterally for 3 months, because of the strong belief that surgery is not indicated unless otitis media with effusion is causing hearing

impairment (defined as equal to or worse than 20 decibels hearing threshold level in the better-hearing ear).

Natural History

Longitudinal studies of otitis media with effusion show spontaneous resolution of the condition in more than half of children within 3 months from development of the effusion. After 3 months the rate of spontaneous resolution remains constant, so that only a small percentage of children experience otitis media with effusion lasting a year or longer. In most children, episodes of otitis media with effusion do not persist beyond early childhood. The likelihood that middle ear fluid will resolve by itself underlies the recommendations made for management of otitis media with effusion.

Environmental Risk Factors

Scientific evidence showed that the following environmental factors may increase potential risks of getting acute otitis media or otitis media with effusion:

- Bottle-feeding rather than breast-feeding infants.
- Passive smoking.
- Group child-care facility attendance.

Because the target child for Guideline recommendations is beyond the age when the choice of breast-feeding versus bottle-feeding is an issue, this risk factor was not considered at length.

Passive smoking (exposure to another's cigarette smoke) is associated with higher risk of otitis media with effusion. Although there is no proof that stopping passive smoking will help prevent middle ear fluid, there are many health reasons for not exposing persons of any age to tobacco smoke. Therefore, clinicians should advise parents of the benefits of decreasing children's exposure to tobacco smoke.

Studies of otitis media with effusion in children cared for at home compared to those in group child-care facilities found that children in group child-care facilities have a slightly higher relative risk (less than 2.0) of getting otitis media with effusion. Research did not show whether removing the child from the group child-care facility helped prevent otitis media with effusion.

Therapeutic Interventions

5. Observation OR antibiotic therapy are treatment options for children with effusion that has been present less than 4 to 6 months and at any time in children without a 20-decibel hearing threshold level or worse in the better-hearing ear.

Most cases of otitis media with effusion resolve spontaneously. Meta-analysis of controlled studies showed a 14 percent increase in the resolution rate when antibiotics were given. Length of treatment in these studies was typically 10 days.

The most common adverse effects of antibiotic therapy are gastrointestinal. Dermatologic reactions may occur in 3 to 5 percent of cases; severe anaphylactic reactions are much rarer; severe hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory adverse effects are rarer still. The potential for the development of microbial resistance is always present with antibiotics.

6. For the child who has had bilateral effusion for a total of 3 months and who has a bilateral hearing deficiency (defined as a 20-decibel hearing threshold level or worse in the better-hearing ear), bilateral myringotomy with tube insertion becomes an additional treatment option. Placement of tympanostomy tubes is recommended after a total of 4 to 6 months of bilateral effusion with a bilateral hearing deficit.

The principal benefits of myringotomy with insertion of tympanostomy tubes are the restoration of hearing to the pre-effusion threshold and clearance of the fluid and possible feeling of pressure. While patent and in place, tubes may prevent further accumulation of fluid in the middle ear. Although there is insufficient evidence to prove that there are long-term deleterious effects of otitis media with effusion, concern about the possibility of such effects led the panel to recommend surgery, based on their expert opinion. Tubes are available in a myriad of designs, most constructed from plastic and/or metal. Data comparing outcomes with tubes of various designs are sparse, and so there were assumed to be no notable differences between available tympanostomy tubes.

Insertion of tympanostomy tubes is performed under general anesthesia in young children. Calculation of the risks for two specific complications of myringotomy with tympanostomy tube insertion showed that tympanosclerosis might occur after this procedure in 51 percent, and postoperative otorrhea in 13 percent, of children.

A number of treatments are not recommended for treatment of otitis media with effusion in the otherwise healthy child age 1 through 3 years.

- **Steroid medications** are not recommended to treat otitis media with effusion in a child of any age because of limited scientific evidence that this treatment is effective and the opinion of many experts that the possible adverse effects (agitation, behavior change, and more serious problems such as disseminated varicella in children exposed to this virus within the month before therapy) outweighed possible benefits.

- **Antihistamine/decongestant therapy** is not recommended for treatment of otitis media with effusion in a child of any age, because review of the literature

showed that these agents are not effective for this condition, either separately or together.

- **Adenoidectomy** is not an appropriate treatment for uncomplicated middle ear effusion in the child younger than age 4 years when adenoid pathology is not present (based on the lack of scientific evidence). Potential harms for children of all ages include the risks of general anesthesia and the possibility of excessive postoperative bleeding.
- **Tonsillectomy, either alone or with adenoidectomy**, has not been found effective for treatment of otitis media with effusion.
- **The association between allergy and otitis media with effusion** was not clear from available evidence. Thus, although close anatomic relationships between the nasopharynx, eustachian tube, and middle ear have led many experts to suggest a role for allergy management in treating otitis media with effusion, no recommendation was made for or against such treatment.
- **Evidence regarding other therapies for the treatment of otitis media with effusion** was sought, but no reports of chiropractic, holistic, naturopathic, traditional/ indigenous, homeopathic, or other treatments contained information obtained in randomized controlled studies. Therefore, no recommendation was made regarding such other therapies for the treatment of otitis media with effusion in children.

Treatment Outcomes

The following table summarizes the benefits and harms identified for management interventions in the target child with otitis media with effusion.

Outcomes of treating otitis media with effusion[1]

Intervention	Benefits[2]	Harms[2]
Observation	Base case.	Base case.
Antibiotics	Improved clearance of effusion at 1 month or less, 14.0% (95% CI [3.6%,24.2%]). Possible reduction in future infections.	Nausea, vomiting, diarrhea (2%-32% depending on dose and antibiotic). Cutaneous reactions (≤5%). Numerous rare organ system effects, including very rare fatalities. Cost. Possible development of resistant strains of bacteria.
Antibiotics plus steroids	Possible improved clearance at 1 month, 25.1% (95% CI [-1.3%,49.9%]).[3] Possible reduction in future infections.	See antibiotics and steroids separately.
Steroids alone	Possible improved clearance at 1 month, 4.5% (95% CI [-11.7%, 20.6%]).[3]	Possible exacerbation of varicella. Long-term complications not established for low doses. Cost.
Antihistamine/ decongestant	Same as base case.	Drowsiness and/or excitability.[4] Cost.
Myringotomy with tubes	Immediate clearance of effusion in all children. Improved hearing.	Invasive procedure. Anesthesia risk. Cost. Tympanosclerosis. Otorrhea. Possible restrictions on swimming.
Adenoidectomy	Benefits for young children have not been established.	Invasive procedure.[4] Anesthesia risk. Cost.
Tonsillectomy	Same as base case.	Invasive procedure.[4] Anesthesia risk. Cost.

[1] The target patient is an otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits.
[2] Outcomes are reported as differences from observation, which is treated as the base case. When possible, meta-analysis was performed to provide a mean and associated confidence interval (CI).
[3] Difference from base case not statistically significant.
[4] Risks were not examined in detail because no benefits were identified.

Algorithm

The notes below are an integral part of the algorithm that follows.

Notes to Algorithm

(A) Otitis media with effusion (OME) is defined as fluid in the middle ear without signs or symptoms of infection; OME is not to be confused with acute otitis media (inflammation of the middle ear with signs of infection). The Guideline and this algorithm apply only to the child with otitis media with effusion. This algorithm assumes followup intervals of 6 weeks.

(B) The algorithm applies only to a child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits (except as noted) who is healthy except for otitis media with effusion. The Guideline recommendations and algorithm do not apply if the child has any craniofacial or neurologic abnormality (for example, cleft palate or mental retardation) or sensory deficit (for example, decreased visual acuity or pre-existing hearing deficit).

(C) The Panel found some evidence that pneumatic otoscopy is more accurate than otoscopy performed without the pneumatic test of eardrum mobility.

(D) Tympanometry may be used as confirmation of pneumatic otoscopy in the diagnosis of otitis media with effusion (OME). Hearing evaluation is recommended for the otherwise healthy child who has had bilateral OME for 3 months; before 3 months, hearing evaluation is a clinical option.

(E) In most cases, otitis media with effusion (OME) resolves spontaneously within 3 months.

(F) The antibiotic drugs studied for treatment of otitis media with effusion (OME) were amoxicillin, amoxicillin-clavulanate potassium, cefaclor, erythromycin, erythromycin-sulfisoxazole, sulfisoxazole, and trimethoprim-sulfamethoxazole.

(G) Exposure to cigarette smoke (passive smoking) has been shown to increase the risk of otitis media with effusion (OME). For bottle-feeding versus breast-feeding and for child-care facility placement, associations were found with OME, but evidence available to the Panel did not show decreased incidence of OME with breast-feeding or with removal from child-care facilities.

(H) The recommendation against tonsillectomy is based on the lack of added benefit from tonsillectomy when combined with adenoidectomy to treat otitis media with effusion in older children. Tonsillectomy and adenoidectomy may be appropriate for reasons other than otitis media with effusion.

(I) The Panel found evidence that decongestants and/or antihistamines are ineffective treatments for otitis media with effusion.

(J) Meta-analysis failed to show a significant benefit for steroid medications without antibiotic medications in treating otitis media with effusion in children.

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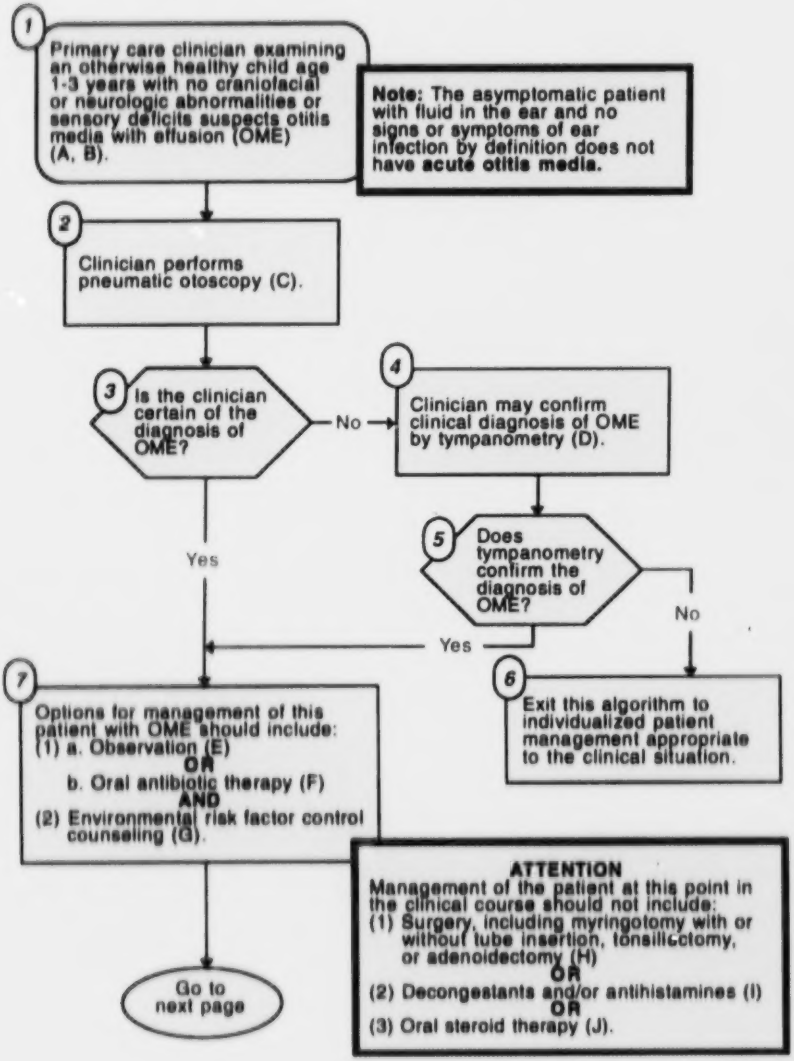
Algorithm for managing otitis media with effusion in an otherwise healthy child age 1 through 3 years


1
Primary care clinician examining an otherwise healthy child age 1-3 years with no craniofacial or neurologic abnormalities or sensory deficits suspects otitis media with effusion (OME) (A, B).
Note: The asymptomatic patient with fluid in the ear and no signs or symptoms of ear infection by definition does not have acute otitis media.
2
Clinician performs pneumatic otoscopy (C).
3
Is the clinician certain of the diagnosis of OME?
No
4
Clinician may confirm clinical diagnosis of OME by tympanometry (D).
Yes
5
Does tympanometry confirm the diagnosis of OME?
No
Yes
6
Exit this algorithm to individualized patient management appropriate to the clinical situation.
7
Options for management of this patient with OME should include:
(1) a. Observation (E)
OR
b. Oral antibiotic therapy (F)
AND
(2) Environmental risk factor control counseling (G).
ATTENTION
Management of the patient at this point in the clinical course should not include:
(1) Surgery, including myringotomy with or without tube insertion, tonsillectomy, or adenoidectomy (H)
OR
(2) Decongestants and/or antihistamines (I)
OR
(3) Oral steroid therapy (J).
Go to next page

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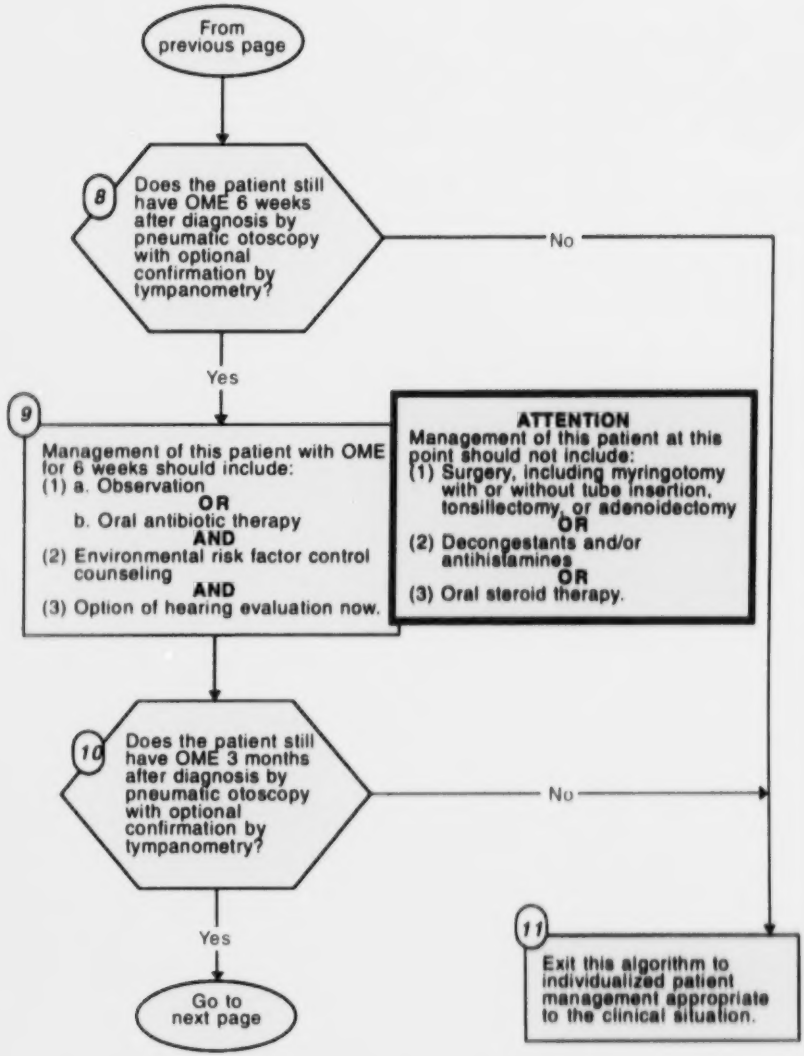
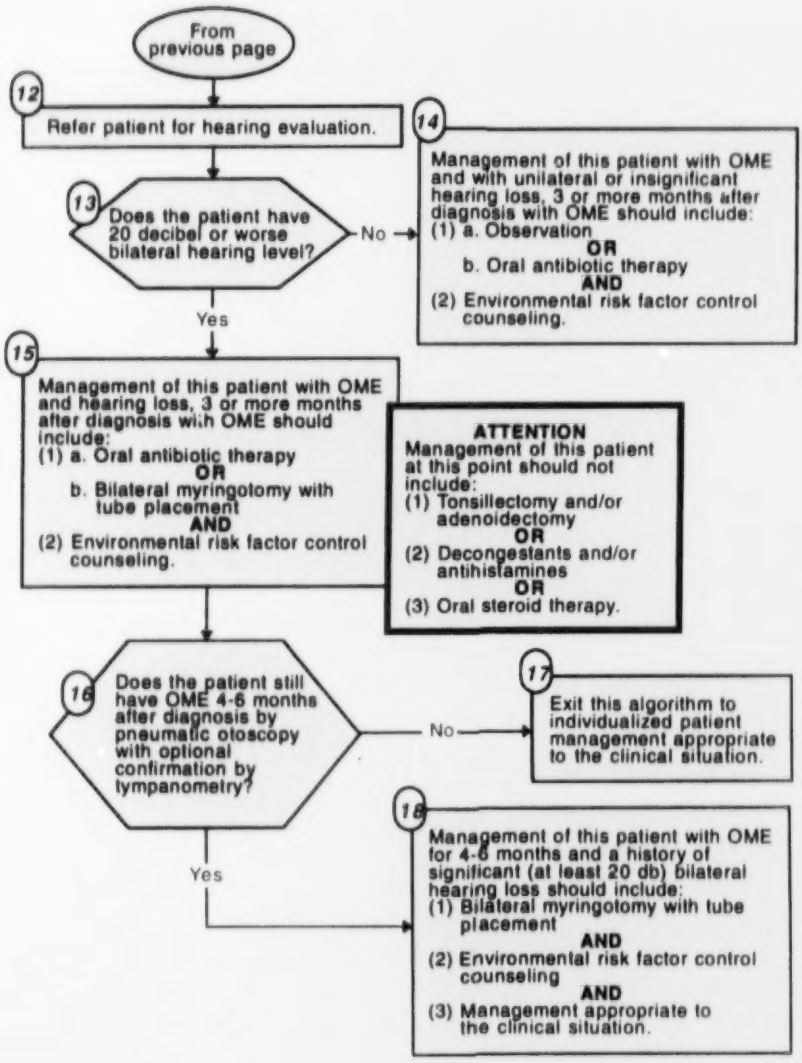
Algorithm (continued)


From previous page
8
Does the patient still have OME 6 weeks after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?
No
Yes
9
Management of this patient with OME for 6 weeks should include:
(1) a. Observation
OR
b. Oral antibiotic therapy
AND
(2) Environmental risk factor control counseling
AND
(3) Option of hearing evaluation now.
ATTENTION
Management of this patient at this point should not include:
(1) Surgery, including myringotomy with or without tube insertion, tonsillectomy, or adenoidectomy
OR
(2) Decongestants and/or antihistamines
OR
(3) Oral steroid therapy.
10
Does the patient still have OME 3 months after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?
No
Yes
Go to next page
11
Exit this algorithm to individualized patient management appropriate to the clinical situation.

Algorithm (continued)


From previous page
12
Refer patient for hearing evaluation.
13
Does the patient have 20 decibel or worse bilateral hearing level?
No
Yes
14
Management of this patient with OME and with unilateral or insignificant hearing loss, 3 or more months after diagnosis with OME should include:
(1) a. Observation
OR
b. Oral antibiotic therapy
AND
(2) Environmental risk factor control counseling.
15
Management of this patient with OME and hearing loss, 3 or more months after diagnosis with OME should include:
(1) a. Oral antibiotic therapy
OR
b. Bilateral myringotomy with tube placement
AND
(2) Environmental risk factor control counseling.
ATTENTION
Management of this patient at this point should not include:
(1) Tonsillectomy and/or adenoidectomy
OR
(2) Decongestants and/or antihistamines
OR
(3) Oral steroid therapy.
16
Does the patient still have OME 4-6 months after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?
No
17
Exit this algorithm to individualized patient management appropriate to the clinical situation.
Yes
18
Management of this patient with OME for 4-6 months and a history of significant (at least 20 db) bilateral hearing loss should include:
(1) Bilateral myringotomy with tube placement
AND
(2) Environmental risk factor control counseling
AND
(3) Management appropriate to the clinical situation.

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Abstract

This *Quick Reference Guide for Clinicians* contains highlights from the *Clinical Practice Guideline, Otitis Media with Effusion in Young Children.* The Otitis Media Guideline Panel, a private-sector panel of health care providers, developed the *Guideline* after comprehensively analyzing the research literature and current scientific knowledge of the development, diagnosis, and treatment of otitis media with effusion in young children.

Specific recommendations are given for the management of otitis media with effusion in young children age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits. The natural history of otitis media with effusion, the functional impairments that may result from otitis media with effusion, and the difficulty of measuring the effects of medical and surgical interventions on long-term outcomes are included. The medical interventions studied involve antibiotic therapy, steroid therapy, and antihistamine/decongestant therapy. The surgical interventions studied involve myringotomy with insertion of tympanostomy tubes, adenoidectomy, and tonsillectomy. Short-term outcomes addressed are resolution of effusion and restoration of hearing.

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Stool SE, Berg AO, Berman S, Carney CJ, Cooley JR, Culpepper L, Eavey RD, Feagans LV, Finitzo T, Friedman E, et al. *Managing Otitis Media with Effusion in Young Children. Quick Reference Guide for Clinicians.* AHCPR Publication No. 94–0623. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. July 1994.

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Middle Ear Fluid in Young Children

Otitis Media with Effusion

Consumer Version
Clinical Practice Guideline
Number 12

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About the Ear and Hearing

The ear has three parts—the outer ear, the middle ear, and the inner ear. The outer ear includes the part outside the head and the ear canal. The eardrum is a small circle of tissue about the size of a fingertip at the end of the ear canal. The middle ear is the space, usually filled with air, behind the eardrum. When a child has middle ear fluid, this is where it is found. A small tube—the eustachian tube—connects the middle ear to the back of the nose. Three tiny bones (the malleus, incus, and stapes) connect the eardrum through the middle ear to the inner ear. The inner ear is further inside the head and is important for hearing and balance.

In a healthy ear, sound waves travel through the ear canal and make the eardrum move back and forth. This makes the three bones in the middle ear move. The movement of these bones sends sound waves across the middle ear to the inner ear. The inner ear sends the sound messages to the brain. But if the middle ear has fluid in it, then the eardrum and the bones cannot move well. This could cause your child to have trouble hearing.

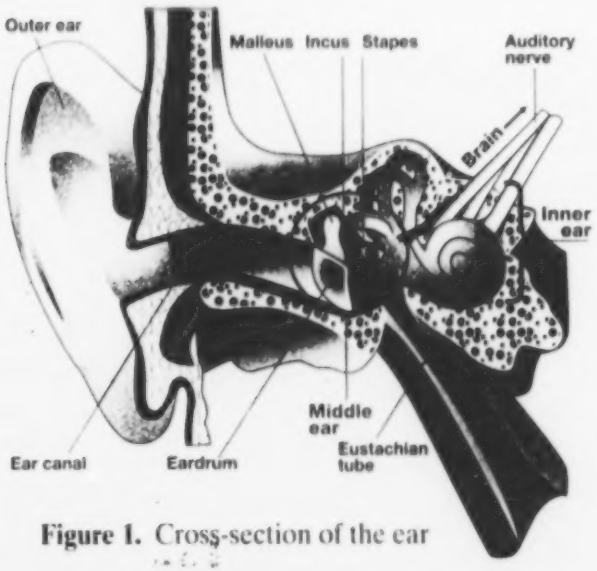

Figure 1. Cross-section of the ear

Middle Ear Fluid in Young Children

Parent Guide

Purpose of This Booklet

This booklet is about middle ear fluid in children ages 1 through 3 who have no other health problems. After reading this booklet you should know more about:

- Causes of middle ear fluid.
- Tests for middle ear fluid and hearing.
- Treatments for middle ear fluid and hearing loss caused by middle ear fluid.
- How to work with your child's health care provider to find the best treatment for your child's middle ear fluid.

Another name for middle ear fluid is otitis media with effusion. Some people also call it "glue ear." Otitis media means middle ear inflammation, and effusion means fluid.

What Is Middle Ear Fluid?

If your child has middle ear fluid, it means that a watery or mucous-like fluid has collected behind the eardrum. Many children get middle ear fluid during their early years. But middle ear fluid is not the same as an ear infection.

- An **Ear Infection** usually happens in only one ear at a time. With a middle ear infection your child may have fever and sharp ear pain. When your health care provider looks into your child's ear, they might see a bulging red eardrum and some fluid in the middle ear.
- **Middle Ear Fluid** is usually found in both ears at once. Most children do not have fever or pain with middle ear fluid. A special test is needed to look for this fluid (see page 4).

What Causes Middle Ear Fluid?

Here are some things that may cause middle ear fluid to happen in your child:

- Past ear infection. It is common for children to have middle ear infections. And some children with middle ear infection later have middle ear fluid.
- Blockage of the eustachian tube (see Figure 1).
- Cold or flu.

There is no one cause for middle ear fluid. Often, your child's health care provider will not know what caused the middle ear fluid.

You may want to use the chart on page 13 of this booklet to keep track of when your child has ear problems and medical treatments.

Why Should I Be Worried About Middle Ear Fluid?

Most health care providers and parents worry that a child who has middle ear fluid in one or both ears may have trouble hearing. Experts do not know how much middle ear fluid affects hearing. Experts are not sure if hearing loss from middle ear fluid can cause delays in learning to talk, and sometimes later on, problems with school work. They do not know for sure what the long-term effects of middle ear fluid are.

How Can Middle Ear Fluid Be Prevented?

Recent studies show that children who live with smokers and who spend time in group child care have more ear infections.

Because some children who have middle ear infections later get middle ear fluid, you might help prevent middle ear fluid by:

- Keeping your child away from cigarette smoke.
- Trying to keep your child away from playmates who are sick.

How Do I Know If My Child Is Affected by Middle Ear Fluid?

Sometimes a child with middle ear fluid does not hear well. The most common complaint of parents whose child has middle ear fluid is that the child turns the sound up too loud or sits too close to the television set. Or sometimes the child does not seem to be paying attention.

Speak to your child's health care provider if you are concerned about your child's hearing. Often, middle ear fluid is found at a regular check-up.

Your child's health care provider may use the first two tests below to check for middle ear fluid.

- A **Pneumatic Otoscope** may be used to check for middle ear fluid (below). With this tool, the health care provider looks at the eardrum. The fluid in the middle ear may be seen behind the eardrum. Even when the fluid cannot be seen, the health care provider can test for fluid with

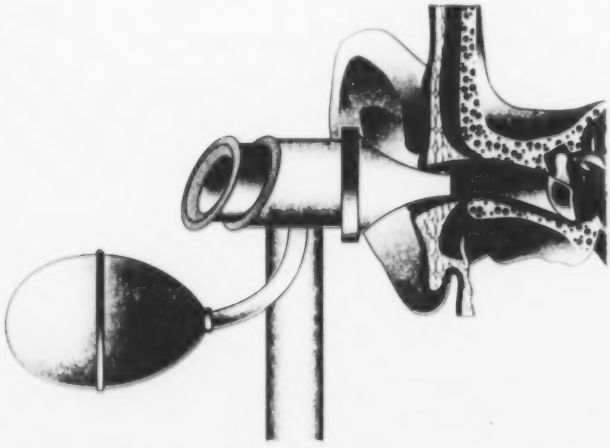

Figure 2. Pneumatic otoscope placed in ear

this tool by blowing a puff of air onto the eardrum to see how well the eardrum moves. The child must be still for this test to work. The child will feel the otoscope in the ear, but the test does not hurt. This test does NOT measure the child's hearing level. Many health care providers feel that the pneumatic otoscope is the best test for middle ear fluid.

- **Tympanometry** is another test for middle ear fluid. Tympanometry helps the health care provider find out how well the eardrum moves. For tympanometry, a soft plug that is about the size of a person's little fingertip is placed snugly into the ear canal. The probe is connected to a machine called a tympanometer. The child hears a low noise for a short time while the machine records how the eardrum reacts. An eardrum with fluid behind it does not move as well as a normal eardrum.

  Like the first test, the child must sit still for this test and will feel the probe in the ear. The test does not hurt. Tympanometry does NOT measure hearing level.

- **Hearing Testing** may be done to see how well your child hears. Hearing testing does not test for middle ear fluid. In this case, it measures if the fluid is affecting your child's hearing level. The type of hearing test used depends on your child's age and listening ability.

How Can Middle Ear Fluid Be Treated?

Middle ear fluid can be treated in many ways. It is important to know that a treatment that works for one child may not work for another. If one treatment does not work, another treatment can be tried. Please discuss each of the treatments listed here with your child's health care provider. Be sure to ask about the possible advantages and disadvantages of each treatment as well. Then, decide with your child's health care provider on the treatment for middle ear fluid.

- **Observation**—Middle ear fluid often goes away without treatment. Some studies show that for most children middle ear fluid clears after 3 to 6 months without treatment.
- **Antibiotic Drug Treatment**—Studies show that middle ear fluid cleared slightly faster in some children given antibiotic drugs than those not given antibiotics. However, antibiotics have some unwanted effects, such as diarrhea, rash, and others (see pages 8 and 9). Also, they can be expensive

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and some children have trouble taking them. For these reasons, you and your child's health care provider may want to try observation first.

Before making a decision, ask your child's health care provider about the costs and possible unwanted effects.

- **Surgery to put "Tubes" in the Ears**—In this minor operation, a small cut is made in the child's eardrum and fluid in the middle ear is gently sucked out. Then a small metal or plastic tube is put into the slit in the eardrum. A general anesthetic is used to put the child to sleep for this operation. When the fluid is removed from the middle ear, the child's hearing returns to its normal level.

Ask your child's health care provider about the costs and possible harms of this surgery.

The tubes are left in place until they fall out, or until your child's health care provider feels that they are no longer needed. About one third (1 out of 3) of children with ear tubes need to have another operation to insert new tubes within 5 years after the first operation.

What Are the Advantages and Disadvantages of Middle Ear Fluid Treatments?

The advantages and disadvantages of treatments for middle ear fluid are listed in the following table. Please discuss these choices further with your child's health care provider.

Treatment	Advantages
Observation	• In about 60 percent of children, middle ear fluid goes away without treatment within 3 months; in 85 percent it goes away within 6 months. There is very little cost and no side effects of observation.
Antibiotic drug	• May increase chance (by about 14 percent) and speed of middle ear fluid going away. • May decrease chance of middle ear infection.
Surgery (tubes)	• Middle ear fluid goes away right away. • Hearing returns to normal right away.

	Disadvantages
	• Middle ear fluid does not go away in about 40 percent of children in 3 months and in about 15 percent in 6 months.
	• Middle ear fluid may not go away. • Unwanted drug effects (such as diarrhea, rash). • Development of drug-resistant strains of bacteria. • Bother of buying and giving drug. • Cost of drug.
	• Temporary discomfort for child. • Risks of anesthesia. • May need to protect ears during bathing and swimming while tubes are in place. • Some children need another surgery to place new tubes in the ears. • Eardrum changes possible. • Time lost to take child for surgery. • Most costly choice.

When Should Middle Ear Fluid Be Treated?

The treatment that your child gets for middle ear fluid depends on:

- How long your child has had middle ear fluid.
- If the fluid is causing hearing problems for your child.

Here are some examples of how your child might best be treated for middle ear fluid.

Remember to discuss all treatments with your child's health care provider. Be sure to ask about the advantages and disadvantages of each treatment.

If your child has had ***middle ear fluid for up to 3 months,*** then your child's health care provider may recommend one of these treatments:

- Observation OR antibiotic therapy. You and your provider may choose observation because antibiotic therapy can cause some unwanted effects.
- Taking steps to prevent middle ear fluid (especially keeping your child away from cigarette smoke).

If your child has had ***middle ear fluid for 3 months or more,*** then your child's health care provider may recommend the following treatments:

- Observation OR antibiotic drugs. You and your provider may choose observation because antibiotic therapy can cause some unwanted effects.

- Taking steps to prevent middle ear fluid (especially keeping your child away from cigarette smoke).

Also

- A hearing test is recommended if your child has had middle ear fluid for 3 months or more. If this shows that your child has a hearing loss in both ears, your child's health care provider may recommend surgery to put tubes in the eardrums.
- Talk to your child's health care provider about any other concerns you have about your child's development—for example, if your child does not seem to be learning to talk on schedule.

If your child has had ***middle ear fluid that has lasted from 4 to 6 months with a hearing loss in both ears,*** then your child"s health care provider may recommend:

- Surgery to put tubes in the eardrums. Tubes in the eardrums should clear the middle ear fluid and return your child's hearing to normal. Discuss this surgery with your child's health care provider.

Also

- Find out if your child's ears should be protected from water after the surgery and when to bring your child back for a checkup.

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What Treatments Are Not Recommended for My Child?

A number of medicines and surgical treatments are not recommended for young children with middle ear fluid.

The medicines not recommended are:

- Decongestants and antihistamines.
- Steroids.

Most studies show that decongestants and antihistamines used together or alone did not improve or cure middle ear fluid. There are not yet enough studies to tell whether steroids can cure or improve middle ear fluid.

The surgical treatments not recommended are:

- Adenoidectomy.
- Tonsillectomy.

There are not yet enough studies to tell if adenoidectomy (removing the adenoids—tissue at the back of the throat behind the nose) cures or improves middle ear fluid in children younger than 4 years old. But it does seem to help older children. Tonsillectomy (removing the tonsils at the back of the throat) has not been shown to cure or improve middle ear fluid in children.

If your child's health care provider suggests one of these surgeries, there may be another medical reason to do the surgery. Ask why your child needs the surgery. If you are still unsure, you may want to talk to another health care provider.

How Do I Keep Track of My Child's Ear Problems?

You may want to use a chart like this one to keep track of your child's ear problems and how they were treated. This may help your child's health care provider to find the cause of the middle ear fluid.

For:

_____

(child's name)

Health care provider's name:

_____

Health care provider's telephone number:

_____

Date and type of middle ear problem fluid or infection)	Treatment	Results

For Further Information

The information in this booklet was based on the *Clinical Practice Guideline, Otitis Media with Effusion in Young Children.* The *Guideline* was developed by a non-Federal panel of experts sponsored by the Agency for Health Care Policy and Research. Other guidelines on common health problems are available, and more are being developed.

For more information about guidelines or to receive more copies of this booklet, call toll-free

800-358-9295

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